DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 433, 447, and 457

[CMS–2258–FC]

RIN 0938–A057

Medicaid Program; Cost Limit for Providers Operated by Units of Government and Provisions To Ensure the Integrity of Federal-State Financial Partnership

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This regulation clarifies that entities involved in the financing of the non-Federal share of Medicaid payments must be a unit of government; clarifies the documentation required to support a Medicaid certified public expenditure; limits Medicaid reimbursement for health care providers that are operated by units of government to an amount that does not exceed the health care provider's cost of providing services to Medicaid individuals; requires all health care providers to receive and retain the full amount of total computable payments for services furnished under the approved Medicaid State plan; and makes conforming changes to provisions governing the State Child Health Insurance Program (SCHIP) to make the same requirements applicable, with the exception of the cost limit on reimbursement.

The Medicaid cost limit provision of this regulation does not apply to: Stand-alone SCHIP program payments made to governmentally-operated health care providers; Indian Health Service (IHS) facilities and tribal 638 facilities that are paid at the all-inclusive IHS rate; Medicaid Managed Care Organizations (MCOs), Prepaid Inpatient Health Plans (PIHPs), and Prepaid Ambulatory Health Plans (PAHPs); Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs). Moreover, disproportionate share hospital (DSH) payments and payments authorized under Section 701(d) and Section 705 of the Benefits Improvement Protection Act of 2000 are not subject to the newly established Medicaid cost limit for governmentally-operated health care providers.

Except as noted above, all Medicaid payments and SCHIP payments made under the authority of the State plan and under waiver and demonstration authorities, as well as associated State Medicaid and SCHIP financing arrangements, are subject to all provisions of this regulation. Finally, this regulation solicits comments from the public on issues related to the definition of the Unit of Government.

DATES: *Effective Dates:* This regulation is effective on July 30, 2007.

Comment Date: Comments only on issues related to Unit of Government Definition (§ 433.50) will be considered if we receive them at one of the addresses provided below, no later than 5 p.m. on July 13, 2007.

ADDRESSES: In commenting, please refer to file code CMS–2258–FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Submit electronic comments on CMS regulations with an open comment period.'' (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2258–FC, P.O. Box 8014, Baltimore, MD 21244–8014.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2258–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Aaron Blight, (410) 786–9560.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public only on issues related to Unit of Government Definition (§ 433.50). You can assist us by referencing the file code CMS–2258–FC and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Electronic Comments on CMS Regulations'' on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

This **Federal Register** document is also available from the **Federal Register** online database through Government Printing Office Access a service of the U.S. Government Printing Office. The Web site address is: *http://www.access.gpo.gov/nara/index.html.*

I. Background

[If you choose to comment only on issues related to Unit of Government Definition (§ 433.50) in this section, please include the caption ''Background'' at the beginning of your comments.]

The Medicaid program is a cooperative Federal-State program established in 1965 for the purpose of providing Federal financial participation (FFP) to States that choose to reimburse certain costs of medical treatment for needy persons. It is authorized under title XIX of the Social Security Act (the Act), and is administered by each State in accordance with an approved Medicaid State plan. States have considerable flexibility in designing their programs, but must comply with Federal requirements specified in the Medicaid statute, regulations, and program guidance.

FFP is available under section 1903(a)(1) of the Act only when there is a corresponding State expenditure for a covered Medicaid service to a Medicaid recipient. Federal payment is based on statutorily-defined percentages of total computable State expenditures for medical assistance provided to recipients under the approved Medicaid State plan, and of State expenditures related to the cost of administering the Medicaid State plan. CMS has the responsibility to ensure that Medicaid payment and financing arrangements comply with statutory intent.

Sections 1902(a)(2), 1903(a) and 1905(b) of the Act require States to share in the cost of medical assistance and in the cost of administering the State plan. Under section 1905(b) of the Act, the Federal medical assistance percentage (FMAP) is defined as ''100 per centum less the State percentage,'' and section 1903(a) of the Act requires Federal reimbursement to the State of the FMAP of expenditures for medical assistance under the plan (and 50 percent of expenditures necessary for the proper and efficient administration of the plan). Section 1902(a)(2) of the Act and implementing regulations at 42 CFR 433.50(a)(1) require States to share in the cost of medical assistance expenditures but permit the State to delegate some responsibility for the non-Federal share of medical assistance expenditures to local sources under some circumstances.

Under Pub. L. 102–234, which inserted significant restrictions on States' use of provider related taxes and donations at section 1903(w) of the Act, the Congress made clear that participation by local sources was limited to: (1) Permissible taxes or donations and (2) intergovernmental transfers (IGTs) and certified public expenditures (CPEs) from units of government. Specifically, units of government were permitted to participate in the funding of the non-Federal share of Medicaid payments through an exemption from provider tax or donation restrictions at section 1903(w)(6)(A) of the Act that reads:

> Notwithstanding the provisions of this subsection, the Secretary may not restrict States' use of funds where such funds are derived from State or local taxes (or funds appropriated to State university teaching hospitals) transferred from or certified by units of government within a State as the non-Federal share of expenditures under this title, regardless of whether the unit of government is also a health care provider, except as provided in section 1902(a)(2), unless the transferred funds are derived by the unit of government from donations or taxes that would not otherwise be recognized as the non-Federal share under this section.

Subsequent regulations implementing Pub. L. 102–234 give effect to this statutory language. Amendments made to the regulations at 42 CFR part 433, at 47 FR 55119 (November 24, 1992) explained:

> Funds transferred from another unit of State or local government which are not restricted by the statute are not considered a provider-related donation or health care-related tax. Consequently, until the Secretary adopts regulations changing the treatment of intergovernmental transfer, States may continue to use, as the State share of medical assistance expenditures, transferred or certified funds derived from any governmental source (other than impermissible taxes or donations derived at various parts of the State government or at the local level).

The above statutory and regulatory authorities clearly specify that in order for an intergovernmental transfer (IGT) or certified public expenditure (CPE) from a health care provider or other entity to be exempt from analysis as a provider-related tax or donation, it must be from a unit of State or local government. Section 1903(w)(7)(G) of the Act identifies the four types of local entities that, in addition to the State, are considered a unit of government: A city, a county, a special purpose district, or other governmental units in the State. The provisions of this final regulation conform our regulations to the aforementioned statutory language and further define the characteristics of a unit of government for purposes of Medicaid financing.

II. Provisions of the Proposed Rule

In the January 18, 2007 proposed rule, we proposed to (1) clarify that only units of government are able to participate in the financing of the non-Federal share of Medicaid expenditures; (2) establish minimum requirements for documenting Medicaid cost when using a CPE; (3) limit health care providers operated by units of government to Medicaid reimbursement that does not exceed the cost of providing covered services to eligible Medicaid recipients; (4) explicitly require that all health care providers receive and retain the total computable amount of their Medicaid payments; and (5) make conforming changes to the SCHIP regulations to make the same requirements applicable, with the exception of the cost limit on reimbursement.

We proposed that the Medicaid cost limit provision of this regulation would apply to Medicaid payments to all governmentally-operated health care providers of Medicaid services, except Medicaid payments to governmentally-operated managed care organizations. We proposed that stand-alone SCHIP program payments made to governmentally-operated health care providers would not be subject to the Medicaid cost limit provision of this regulation. Except as noted above, we proposed that all Medicaid and SCHIP payments made to governmentally-operated providers under the authority of the State plan and under waiver and demonstration authorities would be subject to all provisions of the proposed regulation.

Specifically, under the proposed regulation, we provided the following changes to our existing regulations:

- We proposed to add new language to § 433.50 to define a unit of government to conform to the provisions of section 1903(w)(7)(G) of the Act.
- We proposed to amend the provisions of § 433.51 to conform the language to the provisions of sections 1903(w)(6)(A) and 1903(w)(7)(G) of the Act and to clarify that the State share of Medicaid expenditures may be contributed only by units of government.
- We proposed to include provisions requiring auditable documentation of CPEs that are used as part of the State share of claimed expenditures.
- We proposed that the Secretary would issue a form (or forms) that would be required for governments using a CPE for certain types of Medicaid services where we have found improper claims.
- We proposed to limit reimbursement for governmentally-operated health care providers to amounts consistent with economy and efficiency by establishing a limit of reimbursement not to exceed cost. The proposed Medicaid cost limit in § 447.206 specified that the Secretary will determine a reasonable method for identifying allowable Medicaid costs that incorporates not only OMB Circular A–87 cost principles but also Medicare cost principles, as appropriate, and the

statutory requirements of sections 1902, 1903, and 1905 of the Act.

- We proposed a new regulatory provision at § 447.207 requiring that all health care providers receive and retain the full amount of the total computable payment provided to them for services furnished under the approved State plan (or the approved provisions of a waiver or demonstration, if applicable).
- We proposed to eliminate § 447.271(b), as this provision would no longer be relevant due to the proposed Medicaid cost limit for units of government.
- We proposed a corresponding modification to the Medicaid upper payment limit (UPL) rules found at § 447.272 for inpatient hospital, nursing facility and intermediate care facilities for the mentally retarded (ICFs/MR) services and § 447.321 for outpatient hospital and clinic services, to incorporate by reference the proposed cost limit for providers operated by units of government and to make the defined UPL facility groups consistent with proposed § 433.50. We proposed that formerly established UPL transition periods remain unchanged.
- We proposed to make conforming changes to § 457.220 to mirror § 433.51.
- We proposed to make conforming changes to § 457.628 to incorporate § 433.50.
- We proposed incorporating proposed § 447.207 requiring retention of payments in § 457.628 because this provision applies to SCHIP payments as well as Medicaid payments.
- We developed a form questionnaire to collect information necessary to determine whether or not individual health care providers are units of government.

III. Analysis of and Responses to Public Comments

[If you choose to comment only on issues related to Unit of Government Definition (§ 433.50) in this section, please include the caption ''*Analysis of and Responses to Public Comments*'' at the beginning of your comments.]

We received 422 items of timely public correspondence, containing over 1,000 public comments that raised over 260 individual issues, in response to the January 18, 2007 proposed rule (72 FR 2236 through 2248). The comments came from a variety of correspondents, including professional associations, national and State organizations, physicians, hospitals, advocacy groups, State Medicaid programs, State and local government agencies, and members of the Congress. The majority of commenters urged us to reconsider the proposed criteria for defining a unit of government for purposes of Medicaid State financing and Medicaid reimbursement. The majority of commenters also expressed concern with the administrative burden and cost of properly documenting services to Medicaid individuals. The following is a summary of the comments received and our response to those comments.

A. Unit of Government Definition (§ 433.50)

1C. Comment: A number of commenters asserted that the proposed definition of a unit of government, when applied to specific health care providers, did not produce a definitive conclusion as to whether or not the health care provider qualifies as a unit of government.

1R. Response: The regulation codifies existing statutory criteria for a unit of government that can participate in financing the non-federal share of Medicaid expenditures. This codification of existing Federal statutory requirements was set forth in an effort to assist States in identifying the universe of governmentally-operated health care providers for this purpose.

In this final rule, we are providing that States must apply the statutory and regulatory criteria to each individual health care provider to make initial determinations of governmental status. As we indicated in the proposed rule, we have developed a ''Tool to Evaluate the Governmental Status of Health Care Providers.'' In response to comments on this rule, we have modified that form to allow States to indicate their initial determination of a health care provider's governmental status.

We recognize that there is considerable variation in organizational arrangements and financial relationships between health care providers and units of government, and their treatment under State law. Therefore, application of the statutory and regulatory criteria to specific health care providers will require careful evaluation of the circumstances and applicable State law. We believe the statutory and regulatory criteria provide a consistent framework and yet have sufficient flexibility to accommodate these differences. We see this flexibility as essential to ensuring accurate and consistent determinations within each State.

Because we recognize that this is a complex determination that providers and States may rely upon, we agree that changes in the determination resulting either from a more careful evaluation, or from a change in circumstances, should be applied prospectively only (in the absence of fraud). Thus, to the extent that a State had previously applied the statutory and regulatory criteria to a health care provider's governmental status, in the absence of fraud, CMS intends to consider changes to that status on a prospective basis and does not intend to require retrospective changes in treatment of a provider.

States will be required to maintain these determinations on file and will be required to submit these forms to CMS upon request, in connection with CMS review of Medicaid institutional and non-institutional reimbursement State plan amendments involving governmental providers and with Medicaid or SCHIP financial management reviews. In addition, we intend to request, under our general authority to require supporting documentation for claimed expenditures, and the existing regulatory authority at 42 CFR § 431.16, that States submit a complete list of governmentally-operated health care providers to the Associate Regional Administrator for Medicaid of each State's respective CMS Regional Office with the first quarterly expenditure report due after 90 days of the effective date of the regulation.

If CMS disagrees with a State's initial determination of governmental status, CMS intends to request a timely change in the State's determination prior to pursuing any other measures including, but not limited to, denial of Medicaid reimbursement SPAs and/or disallowances of claims for Federal financial participation. States can appeal such actions through existing appeal processes.

2C. Comment: A number of commenters asked CMS to clarify that the regulation does not affect the transfer of local governmental funding for non-provider specific Medicaid payments by the State and that the regulation allows local governmental entities to voluntarily transfer funds for the benefit of health care providers in their community.

2R. Response: The Federal statute at section 1902(a)(2) of the Act allows States to share their fiscal obligation to the Medicaid program with local governments. Section 1903(w)(6)(A) of the Act specifically recognizes the use of local tax dollars as a permissible source of the non-Federal share of Medicaid payments.

3C. Comment: One commenter expressed concern that CMS's view of what a ''unit of government'' is may evolve over time, thus resulting in inconsistent application of the provisions of the regulation to different health care providers. The commenter argued that the criteria used to

determine what is a ''unit of government'' should be standardized, impartial and result in consistent outcomes.

3R. Response: The provisions of the regulation were designed to ensure a consistent framework to determine status as a unit of government. CMS recognizes that States play a major role in the administration of the Medicaid program and that legal and financial arrangements between health care providers and units of government vary on a case by case basis. Therefore, CMS has developed standardized regulatory criteria, based upon the provisions of Federal statute, that States must apply on a consistent basis to each health care provider within the State to determine whether or not the health care provider is a unit of government.

A State's determination of governmental status must be applied in two ways, to ensure consistent treatment. First, a health care provider, determined by a State to be governmentally-operated, would be eligible to participate in financing the non-Federal share of Medicaid payments (that is, IGTs and CPEs). Second, Medicaid payments to a health care provider, determined by a State to be governmentally-operated, would be limited to the cost of providing services to Medicaid individuals. States must apply the statutory and regulatory criteria regarding governmental status consistently to each health care provider and the initial State determination of governmental status must be consistent. In other words, States cannot consider a health care provider to be governmentally-operated for purposes of participation in IGTs or CPEs, but consider the health care provider non-governmentally operated for purposes of the Medicaid cost limit.

4C. Comment: One commenter suggested that the determination of governmental status of health care providers be made by States, not the Federal government, to identify which health care providers within the State may be involved in IGT and CPE and are subject to the cost limit. The commenter stated that such deference to the States would allow them to make these determinations up front and ensure the continued operation of their Medicaid programs without the threat of retroactive disallowances.

4R. Response: We agree that States should make the initial determination of governmental status by applying the statutory and regulatory criteria to each individual health care provider. We have modified the ''Tool to Evaluate the Governmental Status of Health Care Providers'' to allow States to indicate their initial determination of a health care provider's governmental status.

CMS has responsibility to ensure that the determinations of governmental status made by States are consistent with the Federal statutory and regulatory criteria. To the extent that a State had previously applied the statutory and regulatory criteria to a health care provider's governmental status, absent fraud, CMS intends to consider changes to that status on a prospective basis and does not intend to require retroactive changes in treatment of the provider. If CMS disagrees with a State's initial determination of governmental status, CMS intends to request a timely change in the State's determination prior to pursuing other measures including, but not limited to, denial of Medicaid reimbursement SPAs and/or disallowances of claims for Federal financial participation. States can appeal such actions through existing appeal processes.

5C. Comment: Many commenters recommended that CMS change the proposed definition of unit of government to provide deference to applicable State or local law.

5R. Response: Application of State law in the determination of a health care provider's governmental status for Medicaid purposes must be consistent with the terms of the Federal statute and regulation. This rule would not limit State or local law from recognizing a health care provider as a governmental entity for other purposes.

The provisions of the regulation were designed to ensure consistent application of the Federal statutory instructions regarding what constitutes a unit of government for purposes of Medicaid financing and payment. CMS recognizes that States play a major role in the administration of the Medicaid program and that legal and financial arrangements between health care providers and units of government vary on a case by case basis. Therefore, CMS has developed standardized and impartial regulatory criteria based upon the provisions of Federal statute that States must apply on a consistent basis to each health care provider within the State.

6C. Comment: A number of commenters suggested that CMS allow health care providers currently involved in financing the non-Federal share via IGT or CPE to be grandfathered into the regulation's definition of ''unit of government,'' thereby permitting these health care providers to continue to finance the non-Federal share after the effective date of the provisions of the regulation.

6R. Response: CMS does not view grandfathering to be appropriate for several reasons. First, section 1903(w) contains clear statutory restrictions on States' receipt of funds from non-governmental health care providers to fund Medicaid payments. Indeed, there are severe penalties imposed for such practices. Second, There is nothing in the Medicaid statute that permits non-governmental units to finance the non-federal share of Medicaid payments, and severe statutory penalties. Second, we believe it is important to maintain consistent and equivalent treatment of all States and providers under a uniform regulatory framework.

7C. Comment: Several commenters requested that CMS clarify that the definition of ''unit of government'' is for purposes outlined in the provisions of this regulation only and that CMS does not intend to place restrictions on public status elsewhere. This request was made because the use of the term ''public'' appears in several different contexts throughout the Medicaid statute, and many states employ their own definitions of public status within their Medicaid state plans. For example, federal financial participation is available at the rate of 75 percent of the costs of skilled professional medical personnel of the state agency or ''any other public agency.'' A Medicaid managed care organization that is a ''public entity'' is exempt from certain otherwise applicable solvency standards. ''Public institutions'' that provide inpatient hospital services for free or at nominal charges are not subject to the charge limit otherwise applicable to inpatient services. Moreover, many states adopt special reimbursement provisions in their state plans for ''public hospitals,'' ''governmental hospitals'' or other types of public health care providers.

7R. Response: This final regulation defines a unit of government for purposes of financing the non-Federal share of Medicaid payments and for the application of a new Medicaid upper payment limit on such governmental health care providers.

The reference to ''any other public agency'' in § 432.50 and the exemption from solvency standards for public entities are unaffected by this regulation. As part of this final regulation, the reference to public institutions that provide inpatient hospital services for free or at nominal charges has been deleted in light of the new upper payment limit structure. It is our understanding that virtually every health care provider has a customary charge structure used to bill patients who have sufficient resources and third

party payers, and so no exception to that limit is required. In the unlikely event that a health care provider does not customary charge either patients or liable third parties and thus does not have such a customary charge structure at all, then we would view the customary charge limit to be inapplicable.

8C. Comment: One commenter asked if a health care provider that is operated by a local government which is required by ordinance to levy a tax to support its operations must actually use these tax revenues annually in order to meet the definition of a unit of government.

8R. Response: We would not require that a health care provider use tax revenues in order to be considered a unit of government. Health care providers operated by a local government with taxing authority are always able to directly access tax revenue. This ability to directly access tax revenues through standard appropriation processes and without the need for a contractual arrangement to access such tax revenue is a characteristic that reflects a health care provider's governmental status.

9C. Comment: Several commenters requested that CMS revise the proposed regulatory definition for unit of government. One commenter suggested that the criteria used to define a ''unit of government'' be modified as follows: ''A provider will be recognized as a unit of government if (1) more than twenty-five (25) percent of its services are provided to individuals eligible for Medicaid, the uninsured, or the underinsured; and (2) the provider can reasonably be expected to receive direct government subsidies to maintain operations should the provider be at risk for discontinuing operations.''

Another commenter suggested that the criteria at § 433.50(a)(1)(i) used to define a ''unit of government'' be modified as follows: ''A unit of government is a State, a city, a county, a special district, a health authority, or other governmental unit in the State that has taxing authority, or is specifically established as a unit of government under the State's constitution.''

Finally, another commenter suggested a new subsection (C) to the proposed § 433.50(a)(1)(ii) to read: ''(C) The health care provider, although it does not meet the requirements of subparagraphs (A) or (B), is able to demonstrate to CMS that the sources of its funding are of a nature that would permit a finding that it is a unit of government for purposes of this section.''

9R. Response: The suggested elements are not consistent with statutory criteria regarding the participation of a unit of government in financing the non-federal share of Medicaid expenditures. Section 1903(w)(6) does not refer to entities that provide a particular level of Medicaid services, nor to the potential for general governmental subsidies. It uses the term ''unit of government'' and refers to the use of ''State or local tax revenues.'' While the term ''unit of government'' is not specifically defined, in section 1903(w)(7)(G), there is a definition of ''unit of local government'' that contains a list of entities that generally share the common characteristic of possessing taxing authority. The statutory list includes ''special purpose district'' and ''other governmental unit'' (which are not defined terms and are used to refer to a wide range of entities, some of which do not have taxing authority, direct access to tax revenues, or other indications of governmental status). We read these terms to permit flexibility to include such entities when they share the common characteristic of other listed governmental units of taxing authority (or direct access to tax revenues). We take this reading to ensure consistency with the required use of ''State or local tax revenues'' when a unit of government participates in financing the non-federal share of Medicaid expenditures.

Moreover, we believe that it is essential to have a clear and uniform standard that can be consistently applied in every State and to every provider. Thus we do not see a justification to include open-ended language in the regulatory definition. We have, however, made clear in the final rule our intent to permit flexibility to accommodate entities that do not have independent taxing authority but have direct access to tax revenues. We discuss this further below.

In sum, our reading of the Medicaid statute is that the type of services provided by a health care provider, its reasonable expectation to receive direct government subsidies when at-risk for discontinuing operations, its specific establishment under State constitution, or its funding sources are not characteristics contemplated under the statute as representative of a unit of government that can participate in financing the non-federal share of Medicaid expenditures. The criteria we have set forth are based on our reading of the Medicaid statute, and are intended to permit flexibility to recognize different characterizations of arrangements that fall within a uniform, consistent framework.

10C. Comment: A number of commenters asked CMS to expressly state that the provisions of the regulation have no effect on regulations pertaining to provider taxes.

10R. Response: The provisions of the regulation clarify the statutory exception to the requirements governing health care related taxes and provider related donations. Nothing in this regulation is intended to impact the requirements on health care related taxes and provider related donations. All statutory and regulatory requirements governing health care related taxes and provider related donations still apply.

11C. Comment: One commenter asked CMS to clarify what is meant by the term ''other governmental unit.''

11R. Response: Section 1903(w)(7)(A) of the Act includes in the definition of the term ''unit of local government'' certain specified entities and ''other governmental unit[s] in the State.'' This term is undefined, and we are interpreting it to refer to entities that possess certain qualities that we believe are key to governmental status for purposes of Medicaid financing and payment. In the context of the list as a whole, CMS is interpreting this term to mean entities that are not cities, counties or special purpose districts, but have qualities that are generally shared by those specifically listed entities (and, as discussed below, CMS interprets the broad term ''special purpose district'' in a similar manner). In other words, entities may be considered as units of government for these Medicaid purposes even not specifically listed in the definition if the entities have the same basic qualities as those governmental units that are specifically listed in the statute.

12C. Comment: One commenter observed that it appeared that CMS would determine whether or not a health care provider would be considered a unit of government under the provisions of the regulation. Due to the significant impact (positive or negative) such a determination may have on a health care provider, the commenter proposed that there should be a method of appeal.

12R. Response: In the proposed rule, we anticipated that CMS would make final determinations of governmental status, but in this final rule, we are requiring that States apply the statutory and regulatory criteria to each individual health care provider to make initial determinations of governmental status. To the extent that governmental status affects Medicaid payment to a provider, the provider may have access to State appeal processes.

With respect to the availability of federal financial participation, CMS is responsible to ensure that the

determinations of governmental status made by States are consistent with the Federal statutory and regulatory criteria and may take appropriate action including, but not limited to, denial of Medicaid reimbursement State plan amendments and/or disallowances of claims for Federal financial participation, in the event of noncompliance with any provision of this regulation. States can appeal such actions through existing appeals processes.

13C. Comment: One commenter pointed out that the regulation requires a demonstration that a health care provider is a unit of government in order to be involved in IGTs or CPEs. However, the commenter believes that the regulation exceeded this proposal by requiring a similar demonstration by all governmental health care providers, regardless of any use of IGTs or CPEs.

13R. Response: Under the provisions of this regulation, Medicaid payments to all governmentally-operated health care providers are limited to the cost of providing services to Medicaid individuals. Therefore, all entities that meet the regulatory definition as governmentally-operated health care providers within the State must be identified.

14C. Comment: One commenter asked what is the definition of a ''component unit'' on the consolidated annual financial report referenced in the regulation's preamble, and whether or not an ''enterprise fund'' entry on the consolidated annual financial report would qualify an entity as being considered a unit of government.

14R. Response: The purpose of CMS' use of the term component unit was to assist States in identifying health care providers that are an integral part of a unit of government. A component unit that appears on the consolidated annual financial statement of a unit of government because the unit of government is responsible for the component unit's expenses, liabilities and deficits would be indicative that the component unit may be considered a unit of government. It is our understanding that enterprise funding is an accounting method used to account for operations intended to be financed and operated like private busineses, with costs covered primarily through user fees or otherwise kept on a distinct basis. To the extent that this accounting method is applied to an entity that would otherwise be accounted for as a component unit on the consolidated financial statement, the use of enterprise accounting should not make a difference in that status.

15C. Comment: One commenter noted the regulation's language requiring that a unit of government must have a role in funding a health care provider's expenses, liabilities, and deficits in order for the health care provider to be considered a unit of government. However, the commenter indicated that it was not clear whether the unit of government must have full responsibility for all three of these areas or whether partial responsibility for some of these areas would be sufficient. The commenter opines that regardless of the answer to that question, CMS would still find it necessary to conduct individualized investigation and analysis, regardless of information collection, making the form unnecessary and duplicative. Therefore, the commenter recommends withdrawal of the form.

15R. Response: For a health care provider to be considered as a unit of government, the operating unit of government must have full responsibility for funding a health care provider's expenses, liabilities, and deficits in order for the health care provider to be considered a unit of government. We do not intend this to preclude an enterprise funding accounting method, as discussed above, where the operation of the health care provider is intended to be primarily funded through user fees. But this definition would not include health care providers that are independent legal entities that contract with a unit of governnment, even if the contract includes partial funding among its terms.

16C. Comment: A number of commenters argued that principles of federalism, rooted in the Tenth Amendment to the Constitution, support a State's right to determine what constitutes a unit of government within the State and argued that the provisions of this regulation would intrude upon the State's ability to organize itself as deemed necessary.

16R. Response: The provisions of this regulation concern the question of whether, in determining the amount of federal funds to which a State is entitled under the Medicaid program, transfers of funds to the State government from a Medicaid health care provider that is an entity other than the State government will be exempt from consideration as a provider tax or donation, and when expenditures of such an entity can be certified as ''public expenditures'' that constitute the non-Federal share of Medicaid expenditures. It also sets forth a consistent definition of entities that must be treated as governmental in determining the reasonableness of Medicaid payment rates.

The Tenth Amendment to the U.S. Constitution does not accord any special privileges with respect to Medicaid funding, and the provisions of this regulation would not affect a State's ability to organize itself for other purposes.

Nevertheless, we have determined in response to comments to provide States with the primary role in identifying units of government using the criteria set forth under this regulation, as long as the identification is consistently applied. This responsibility falls within the overall duty to document claims for federal financial participation.

17C. Comment: A number of commenters noted the distinction between the terms ''unit of local government,'' found at Section 1903(w)(7)(G), and the term ''units of government within a State,'' found at Section 1903(w)(6)(A) of the Act. One such commenter identified a recent decision from the Departmental Appeals Board (Ga. Dept. of Comty. Health, DAB No. 1973 (2005)) in an effort to highlight the differences in these terms. These commenters assert that Congress deliberately left ''units of government'' undefined in order to afford States discretion in how they choose to finance their Medicaid programs.

17R. Response: We have considered both statutory terms in developing criteria to determine if an entity is a unit of government for purposes of transferring funds or certifying expenditures under Medicaid; we have looked at what characteristics were generally shared by the entities specifically referenced in the statute, and we have also considered what the underlying intent appears to be. In section 1903(w)(6)(A) of the Social Security Act, Congress clearly expressed the intent that these entities must be able to use ''funds derived from State or local taxes (or funds appropriated to State university teaching hospitals) * * *'' Unlimited discretion is not consistent with the plain language of this provision. The cited DAB decision primarily rested on a different issue, not changed by this rule, the limitation on protected Medicaid financing by units of government to those ''in the State.''

18C. Comment: One commenter suggested that the proposed changes in the provisions of this regulation are beyond mere clarifications of existing policy and therefore could not be implemented on a retrospective basis without violating the notice and comment requirements of the Administrative Procedure Act.

18R. Response: The provisions of the regulation will be effective 60 days after publication of the final regulation and therefore are not being implemented on a retrospective basis. Moreover, all requirements of the Administrative Procedure Act are being met. The publication as a notice of proposed rulemaking with a 60-day comment period afforded all interested parties the opportunity to provide input and comment. CMS has fully considered all public comments received during that 60-day period in the development of the final provisions of the regulation.

19C. Comment: One commenter suggested that provisions of the regulation may violate the Spending Clause of the U.S. Constitution. This commenter argues that the regulatory change in the definition of ''unit of government'' will dramatically and adversely affect a State's level of funding for Medicaid, which would effectively ''coerce'' the States in a manner that contradicts the Spending Clause (see *South Dakota* v. *Dole,* 483 U.S. 203, 207, 211 (1987)).

19R. Response: The provisions of this regulation concern the question of whether, in determining the amount of federal funds to which a State is entitled under the Medicaid program, transfers of funds to the State government from a Medicaid health care provider that is an entity other than the State government will be entitled to exemption from consideration as a provider tax or donation, and when expenditures of such an entity can be certified as ''public expenditures'' that constitute the non-Federal share of Medicaid expenditures.

This rule also sets forth a consistent definition of entities that must be treated as governmentally-operated in determining the reasonableness of Medicaid payment rates. It does not ''coerce'' the State to take any action outside of the scope of the Medicaid program enacted under the Spending Clause. Nor do the provisions of this regulation affect rights of others outside of the operation of the Medicaid program.

20C. Comment: A number of commenters expressed that section 1903(w)(6)(A) was a provision that Congress included in the Act which was intended to limit CMS' authority to regulate the financing sources for the non-Federal share of the Medicaid program. Commenters made this point to suggest that it is inappropriate for CMS to issue regulatory provisions governing sources of State or local funds used to satisfy the non-Federal share.

20R. Response: Section 1903(w)(6)(A) of the Act carved out an exception to the financing restrictions that Congress itself enacted in section 1903(w). Section 1903(w)(6)(A) of the Act has very specific language and we believe that the provisions of this regulation give meaning to each of the terms used in that section. This regulation interprets and implements those terms. The language of section 1903(w)(6)(A) of the Act cannot reasonably be read as a general prohibition on CMS review to determine if the criteria of section 1903(w)(6)(A) of the Act have been met.

21C. Comment: A number of commenters noted that by Executive Order binding on CMS, federal agencies must ''closely examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and shall carefully assess the necessity for such action.'' Executive Order 13132, 64 FR at 43256 (August 4, 1999). Similarly, wherever feasible, agencies must ''seek views of appropriate State, local and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities'' and must ''seek to minimize those burdens that uniquely or significantly affect such governmental entities, consistent with regulatory objectives.'' Executive Order 12866, Sec. l(b)(9), as amended 58 FR 51735 (February 26, 2002). The commenters assert that CMS has failed to respect those mandates here.

21R. Response: We believe we have fully met the requirements of the cited Executive Orders. First, the provisions of this regulation have been the result of years of review and reflection on State submissions and financial reviews of State programs. Second, this regulation has been issued after advance notice of its general terms was issued in Presidential budget documents, and numerous discussions with State officials and other interested parties. Third, affected parties have had full opportunity for input through the informal rulemaking procedures under the Administrative Procedure Act. These processes have indeed significantly affected the proposed and final regulation. But these processes do not supersede CMS responsibilities to safeguard the integrity of the Medicaid program, and ensure that federal dollars are spent only when matched by actual, documented, expenditures from State or local non-federal funds that meet applicable criteria under the law.

22C. Comment: Several commenters noted that many governments have organized or reorganized public hospitals into separate entities in order to provide them with the autonomy and flexibility to deliver more efficient and higher quality health care. It was asserted that because some of these hospitals would not be recognized as governmental under the regulation, they will not be as able to fulfill their mission of delivering accessible care in an efficient and effective manner, nor will they be permitted to finance the non-Federal share of Medicaid payments via IGT or CPE. Many commenters also expressed concern that existing financing arrangements involving IGTs or CPEs from certain health care providers would be undone because some of these health care providers may not be considered units of government under the regulation. To the extent such IGT or CPE arrangements need to change after the provisions of the regulation are effective, the funding for these health care providers will be at risk. This concern was particularly emphasized relative to any affected safety net health care providers because of their services to our nation's most vulnerable populations.

22R. Response: A health care provider that is not recognized as governmentally-operated under the Federal statutory and regulatory criteria will not be subject to the cost limitation on Medicaid payments. Therefore, such health care providers may receive Medicaid payments up to the applicable regulatory upper payment limit, to the extent States use permissible sources of non-federal share funding to make such payments. Furthermore, such health care providers would not be subject to obligations to fund the non-federal share of a State's Medicaid program. To the extent that such a health care provider was previously obligated to fund certain Medicaid payments, total Medicaid revenues to that facility can be sustained through alternative permissible sources of non-federal share funding. These health care providers may realize significantly greater net Medicaid revenues if State or local government funding sources are utilized to fund the non-federal share historically financed by the health care providers. Therefore, such health care providers will not necessarily be affected in their mission to deliver accessible care in an efficient and effective manner.

Indeed, the provisions of the regulation were actually designed to protect health care providers. Non-governmentally operated health care providers, including many of the ''public'' safety net providers, are not affected by the cost limit provision of the regulation and therefore, may continue to receive Medicaid payments

in excess of the cost of providing services to Medicaid individuals within existing Federal requirements. Governmentally operated health care providers may receive the full cost of furnishing Medicaid services, which could mean rates that substantially exceed those available to other classes of facilities.

Moreover, § 447.207 protects health care providers because it requires that health care providers be allowed to fully retain their Medicaid payments. This requirement assures that payments to providers are actual expenditures and are available to support the provision of services to Medicaid beneficiaries. These requirements demonstrate the Federal government's intent to protect the nation's public safety net providers and the ability of those providers to serve our nation's most vulnerable populations.

23C. Comment: Many commenters pointed out that there are public hospitals that have been involved in financing the non-Federal share via IGT or CPE for years without any objection from CMS. Under the provisions of the regulation, however, certain public hospitals would no longer be permitted to finance the non-Federal share via IGT or CPE because they would not qualify as units of government. These commenters found it unreasonable that CMS would eliminate long-standing funding arrangements for Medicaid services provided at these hospitals, saying that the elimination of Federal funding for such hospitals could be catastrophic. These commenters asserted that the loss of Federal funding could result in increased costs to State or local government, increased provider taxes, cuts in Medicaid eligibility, or reductions in Medicaid coverage or reimbursement.

23R. Response: The numerous comments regarding particular health care provider's inability to continue financing the non-Federal share of Medicaid payments through IGTs, or CPEs, indicates that States have been ignoring the statutory limitation to ''units of government'' in the provision permitting IGTs or CPEs without regard to provider tax and donation rules. Instead, it appears many States relied on a health care provider's ''public'' mission as sufficient evidence of eligibility to make IGTs or CPEs. By doing so, the States imposed an additional burden on these non-governmental safety net providers to shoulder the fiscal responsibility of state and local units of government under the Medicaid statute.

In other words, the provisions of the regulation were actually designed to protect health care providers, including the safety net providers. Under the provisions of the regulation, governmentally-operated health care providers are assured opportunity to receive full cost reimbursement for serving Medicaid individuals. Non-governmentally-operated health care providers, including many of the ''public'' safety net hospitals, are not affected by the Medicaid cost limit provision of the regulation and therefore, may continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements. Moreover, the final rule provides that payments to these health care providers cannot be diverted, but must be retained by the providers and available to support provider services.

24C. Comment: One hospital that would be considered a unit of government under the provisions of the regulation suggested that even though it qualifies as a unit of government, it would be adversely affected by the unit of government definition because the regulation would disqualify other hospitals in the State from participating in IGTs and CPEs. This disqualification, the commenter asserts, would jeopardize the fiscal health of the hospital that qualifies as a unit of government.

24R. Response: This final rule would permit States to pay governmental providers the full cost of furnishing covered services to Medicaid beneficiaries, and thus a governmental hospital need not incur any loss from participation in the Medicaid program. To the extent certain health care providers are no longer eligible to participate in the IGT process, no loss of Federal funds will occur for such affected health care provider if State and/or local government satisfy the non-Federal share of the Medicaid payments historically funded by non-governmentally-operated health care providers. Moreover, nothing in statute or regulation requires States to increase a governmentally-operated hospital's fiscal obligation to Medicaid in order to supplant non-Federal obligations historically satisfied by non-governmentally-operated hospitals.

25C. Comment: One commenter noted that recently CMS has expanded financial controls over the CPE process by requiring reconciliations to a cost report and instruction on how a certified public expenditure is calculated. This commenter questioned how converting ownership status to private-owned for those health care providers who have been historically considered as public-owned by CMS under the regulation's provisions would increase financial controls.

25R. Response: CMS is not ''converting'' ownership status of any facilities as a result of the provisions of this regulation but this final rule will ensure more accurate determinations of governmental status based on the underlying facts and the statutory and regulatory requirements. These determinations will identify the universe of governmentally-operated health care providers for purposes of the new upper payment limit and of participation in financing of the non-Federal share of Medicaid payments. The final rule will ensure that claims for federal expenditures are supported by actual state and local expenditures.

26C. Comment: Some commenters suggested that the regulation's definition of a unit of government will undermine marketplace incentives to operate public health care providers through independent entities. This argument postulates that public hospitals, which fill a unique role in serving the poor and uninsured, were historically operated as a department of the state or local government, with associated bureaucratic controls. Over time, however, many governments that had previously operated public hospitals as integrated governmental agencies began searching for new ways to organize and operate these entities to provide them more autonomy and equip them to better control costs and compete in a managed care environment. Acknowledging the wide variance in the structure of these public hospitals today, the commenters suggest that the provisions of the regulation would only permit health care providers following the most traditional model to be considered units of government, thus reversing incentives to make operating enhancements resulting from the devolution of provider control from a government to a non-governmental entity.

26R. Response: The provisions of the regulation were not designed to undermine marketplace incentives to give ''public'' health care providers increased autonomy. We recognize, however, that some changes in organizational structure may require adjustment of arrangements to finance Medicaid expenditures.

For example, a provider that is truly independent of any governmental unit (for example, a former county hospital leased by a private corporation) would not be permitted to contribute the non-federal share of Medicaid expenditures. To the extent that such a provider had claims for covered services to Medicaid eligible individuals, a governmental

unit such as the county) that pays for such care can certify a public expenditure (at rates under the approved State plan) to support a claim for federal financial participation.

We believe the uniform regulatory definition of a unit of government in this final rule will guide States, localities and providers in arranging their relationships to comply with the Medicaid statute. At the same time, as discussed above, the uniform regulatory definition will protect the fiscal integrity of the program by ensuring that claims for federal financial participation are supported by actual non-federal expenditures that meet statutory requirements. And this rule will protect health care providers and ensure that Medicaid payments are available for covered care to eligible individuals.

27C. Comment: Multiple commenters requested that CMS clarify the unit of government definition's applicability to other areas of Medicaid.

27R. Response: This regulation directly concerns only the treatment of financial transactions that involve entities that meet the definition of a unit of government. This rule attempts to set forth a consistent definition for that purpose. But this rule does not address the definition of a unit of government or public agency for other purposes. Whether we would interpret other requirements similarly may depend on the context and circumstances of those requirements.

28C. Comment: Many commenters stated that specific entities within a State would not qualify as units of government under the provisions of the regulation. Other commenters requested that CMS affirmatively specify that certain named health care providers could continue to fund the non-federal share of Medicaid payments through IGTs and/or CPEs. To the extent such entities have been involved in financing the non-Federal share of Medicaid payments, such entities would be required to change financing arrangements and would be at risk of losing Medicaid funding for their services.

One commenter observed that Local Education Agencies (LEAs) without taxing authority may be currently involved in certified public expenditures (CPEs) but may also be fiscally independent from county governments. The commenter is concerned that such a LEA would not qualify as a unit of government under the provisions of the regulation, eliminating existing CPE practices and placing school based services or school-based administrative claims at risk. Several commenters stated that the definition of ''unit of government'' would no longer permit many public health care providers that operate under public benefit corporations from helping States finance the non-Federal share of Medicaid funding.

Several commenters stated that the definition of ''unit of government'' would no longer permit many State universities from helping States finance the non-Federal share of Medicaid funding.

One commenter opined that under the regulation's definition of governmental providers, Regional Councils of Governments would not be eligible to provide matching funds for the non-Federal share of Medicaid payments. The commenter states that the Federal government created Councils of Governments to assist in the implementation of programs such as Medicaid, that State and local governments should have the prerogative of decision making with respect to operational responsibility for Medicaid, and that the unit of government definition compromises such arrangements at the State and local levels. One commenter made a suggestion that CMS modify the provisions of the regulation to recognize the public status of public community hospitals organized and operated in the State of Mississippi under Miss. Code Ann §§ 41–13–10, et seq. (1972 and supplements) and include these hospitals under the unit of government definition.

A number of commenters wrote concerning the impact the regulation's definition of unit of government may have on ''public entity'' (PE) community health centers (CHCs), which may current certify public expenditures within a State. PE model CHCs are created by units of government but generally do not have taxing authority. However, they must adhere to governance rules established by the Health Resources and Services Administration (HRSA) that mandate a Board of Directors comprised of at least 51 percent users of the CHC. Each of the PE models has a slight variation in governance structure. The commenters are concerned that some of these PE model CHCs would not be recognized under the provisions of the regulation as a unit of government and would therefore lose the federal funding based on expenditures they are currently certifying via the CPE process.

One commenter wanted to know whether or not a State's regional school districts, charter schools, and municipal school districts would qualify as units of government under the provisions of the regulation.

28R. Response: As these comments point out, there is a wide variety in the organization of, and relationship between, governmental and non-governmental entities. We cannot predetermine which entities have governmental status for purposes of participating in financing the non-federal share of Medicaid expenditures, or application of the governmental upper payment limits. This regulation establishes criteria assist States in making those determinations in order to document claimed expenditures for purposes of obtaining federal financial participation.

As discussed previously, some of the commenters appear to be confusing public mission with governmental status. Neither section 1903(w)(6)(A) nor section 1903(w)(7)(G) of the Act refer to a public mission; instead these sections refer to specific governmental entities, governmental status, and the use of State and local tax revenues. Moreover, while a provider determined to be non-governmental cannot participate in financing the non-federal share of Medicaid expenditures, units of government that fund covered services to Medicaid eligible individuals at the provider can certify a public expenditure (at rates under the approved State plan) to support a claim for federal financial participation.

29C. Comment: A number of commenters questioned the proposed provision at § 433.50(a)(1)(ii)(B) allowing a health care provider without taxing authority to be considered a unit of government only if the government with taxing authority has a legal obligation to fund the health care provider's expenses, liabilities, and deficits. These commenters argued that some providers were deliberately designed by the government to be autonomously funded yet also possess governmental attributes under applicable State or local laws. It was therefore asserted that the provisions of the regulation penalize providers that have reduced their reliance on taxpayer support and creates incentives to redesign provider structures into a less flexible, more inefficient governmental form that is more dependent on the taxpayer.

29R. Response: The provisions of the regulation were not designed to penalize governmentally operated health care providers that have reduced their reliance on taxpayer support. Nor is the regulation intended to create incentives to redesign health care provider structures into a less flexible, more inefficient governmental form that is more dependent on the taxpayers.

We have modified the regulation at § 433.50 to address concerns regarding taxing authority as a requirement for an entity to be considered a unit of government. The regulation has been revised to indicate that a unit of government must have either taxing authority or direct access to tax revenues. We have added the phrase ''has direct access to tax revenues'' to recognize as governmental those entities that do not have taxing authority, and may not have immediate needs for tax support, but do have direct access to tax revenues of a related unit of government because of the direct responsibility of that unit of government for the provider.

30C. Comment: Two commenters raised questions about special purpose districts. One asked CMS to clarify what is meant by the term ''special purpose district,'' while another stated that the provisions of the regulation seemed to eliminate the ability of special purpose districts to participate in funding Medicaid.

30R. Response: As noted previously, we interpret the broad statutory language to rely on the characteristics of the entity in question rather than on its label. We believe that the statutory reference to special purpose district has to be read in the statutory context to refer to an entity that resembles the other entities in the list. By grouping ''special purpose districts'' with ''cities'' and ''counties,'' we read the statute to refer to special purpose districts that share qualities generally held by cities and counties. One of those qualities, for example, is authority to impose taxes or directly access tax revenues. While there may be some entities that a State calls special purpose districts that do not have such authority, in context we read the statute to refer only to those entities that have qualities similar to cities and counties.

31C. Comment: One commenter discussed hospital authorities, which have been given certain governmental powers but not the authority to tax in a State. In fact, the State's legislature specifically granted local governments the power to agree by contract with the hospital authorities to utilize tax revenues for their services. The commenter expresses concern that under the provisions of the regulation, all hospital authorities in the State would not qualify as a unit of government, per the proposed language about contracts at § 433.50(a)(1)(ii)(B).

31R. Response: The regulatory text at § 433.50(a)(1)(ii)(B) specifies that a contractual arrangement with the State or local government is not the ''primary or sole basis for the health care provider to receive tax revenues.'' This language suggests that the presence of a contractual arrangement does not automatically preclude a health care provider from being considered a unit of government. However, if the only way for a health care provider to access general tax revenue is under a contract for services with a unit of government, then the health care provider is likely not a unit of that government. States must apply all statutory and regulatory criteria to each individual health care provider to make initial determinations of governmental status.

32C. Comment: One commenter wrote that the regulation's preamble on certified public expenditures indicates that the ''plain meaning of the Act'' precludes not-for-profit entities from financing the non-Federal share. The commenter expresses that there is no support provided for this statement in this section of the regulation. Therefore, the commenter asks CMS to provide relevant statutory provisions supporting the conclusion.

32R. Response: Medicaid is a shared responsibility between Federal and State government. State governments may share their fiscal obligation to the Medicaid program with local governments according to the instruction of Congress. Under Public Law 102–234, the Congress made clear that States may allow governmental health care providers to participate in a State's fiscal obligation to the Medicaid program through the use of intergovernmental transfers and certified public expenditures.

The provision of the regulation regarding certified public expenditures is a clarification to existing Federal statutory instruction at section 1903(w)(6)(A) of the Act. Consistent with this explicit statutory instruction, a certified public expenditure (CPE) means that State or local tax dollars were used to satisfy the cost of serving Medicaid individuals (and the cost of providing inpatient and outpatient hospital services to the uninsured for purposes of Medicaid DSH payments).

Under the provisions of the regulation, all health care providers maintain some level of ability to participate in the CPE process. Governmentally-operated health care providers are able to certify their costs without having to demonstrate that State or local tax dollars were used to provide Medicaid services. This policy is based on the fact that governmentally-operated health care providers always have the ability to access State and/or local tax dollars as an integral component of State or local government. Governmentally-operated health care providers need only produce cost documentation via national, standardized cost reporting to receive Federal matching funds as a percentage of such allowable Medicaid (and DSH) costs.

Non-governmentally-operated health care providers may also produce cost documentation to support the costs of providing services to Medicaid individuals (and certain uninsured costs for purposes of Medicaid DSH payments). However, in order to maintain consistency with the Federal statutory instruction governing CPEs, a State or local government must actually certify that tax dollars were provided to the non-governmentally-operated health care provider. Federal matching funds can be available, to the extent consistent with the approved State plan, for allowable Medicaid costs incurred by the non-governmentally-operated health care provider that are funded with such State and/or local tax support.

33C. Comment: One commenter requested that if the proposed definition of unit of government is adopted, that CMS clarify its interpretation of nonpublic provider.

33R. Response: The term ''nonpublic provider'' is referenced in section 1903(w)(3)(B) of the Act for purposes of evaluating a broad-based health care related tax. This rule addresses only the governmental exception from provider tax and donation rules, and does not address the substance of the provider tax and donation rules. Changes to those rules are outside the scope of the proposed rule and would be more appropriately addressed in separate rulemaking. Therefore, we do not find it necessary to further clarify the term ''nonpublic provider'' in this rule.

34C. Comment: Multiple commenters described concerns regarding Medicaid Behavioral Health Plans that have been characterized as government entities by a county or group of counties to manage the risk-based contract. The commenters stated that under this arrangement, local dollars are paid to the health plan for Medicaid match and these funds are then submitted to the State to cover the match. The commenters are concerned that this IGT agreement does not meet the definition of a unit of government since the plans were not given taxing authority and the counties do not have the legal obligation of the plan's debts. The commenters requested that the proposed regulation explicitly state that local dollars will be considered valid IGTs if they originated at a unit of government regardless of the entity that submits the payment to the State.

34R. Response: Entities that are not units of government can not make IGTs or CPEs regardless of where the entity

gets funding. Section 1903(w)(6)(A) specifically refers to funding transferred or certified from ''units of government'' and does not provide a basis for tracing the source of funding transferred or certified from other entities. Any transfer of funds from a non-governmentally-operated health care provider to a State constitutes a provider-related donation, not an intergovernmental transfer. In the situation discussed by commenters, the parties may want to explore restructuring their relationship to provide that the local unit of government make an IGT to the State directly.

35C. Comment: Many commenters disagreed with any suggestion that not-for-profit status in and of itself should disqualify an entity as a unit of government. The commenters noted that many traditional public health care providers are nonprofit corporations under Section 501(c)(3) of the Internal Revenue Code, and these health care providers not only have a public-oriented mission but are subject to public oversight and receive substantial financial support from the communities in which they operate.

Further, they argued that the fact that an enterprise is organized in corporate form is not inconsistent with its being a public entity. The commenters cited examples of federal public entities that operate in corporate form, including the Federal Deposit Insurance Corporation, the Tennessee Valley Authority, and the Communications Satellite Corporation.

Similarly, multiple commenters observed that frequently, State laws creating hospital districts allow the hospital to operate as a 501(c)(3) nonprofit corporation, while the authorizing legislation vests the hospital with governmental status. The commenters assert that hospitals operated under these hospital district laws have, until this rulemaking, been viewed as public hospitals.

Many other commenters stated that nonprofit corporations have many attributes of public entities and should therefore be allowed to qualify for purposes of financing the non-Federal share of Medicaid. The commenters remarked that not for profit corporations are required to serve a ''public interest,'' 26 CFR. § 1.501(c)(3)–l(d)(1)(ii). They note that unlike for-profit corporations, there are no shareholders, and no private persons can have any ownership interest in the nonprofit corporation. Nonprofit corporations can have ''members'' (though this is not required), but members have no ownership interest in the assets or business of the nonprofit corporation. Further, the commenters observe that when a nonprofit corporation terminates its operations, its assets must (depending on the applicable State law) be contributed either to another nonprofit or to the federal, State, or local government for a public purpose. In other words, once assets are committed to a benevolent purpose being carded out through a nonprofit corporation, those assets must remain available for a benevolent purpose. The commenters also point out that localities or hospital districts frequently choose to organize a hospital as a 501(c)(3) organization in order to ensure that the hospital will be able to accept private charitable donations, which would be permitted under Section 1903(w) of the Act. These commenters essentially argue that the public-oriented nature of non-profit corporations should be sufficient to allow such corporations to be considered tantamount to units of government for purposes of Medicaid financing.

35R. Response: While it may be that nonprofit corporations have some public service qualities that governmental units have, there is no question that they are not units of government. Section 1903(w) contains severe penalties on the use of donations from health care providers to finance the non-federal share of the Medicaid program, but includes an exception for funding transferred or expenditures certified by units of government. There is nothing in the Medicaid statute that would indicate non-governmental ''public'' units could help a State finance its share of Medicaid payments.

Medicaid is a shared responsibility between Federal and State government. State governments may share their fiscal obligation to the Medicaid program with local governments according to the instruction of Congress. Under Public Law 102–234, the Congress made clear that States may allow governmentally-operated health care providers to participate in a State's fiscal obligation to the Medicaid program through the use of intergovernmental transfers and certified public expenditures. However, the Congress was also clear that States may not receive funds from non-governmentally-operated health care providers for purposes of financing Medicaid payments.

This final rule will assist States in identifying the universe of governmentally-operated health care providers that could receive Medicaid revenues up to the full cost of providing services to Medicaid individuals and clarifies which types of health care providers can participate in financing of the non-Federal share of Medicaid payments.

36C. Comment: A number of commenters noted that the Medicare regulation governing location requirments for determining whether a facility has provider-based status recognize that a unit of State or local government may ''formally grant governmental powers'' to a health care provider organized as a public or nonprofit corporation. See 42 CFR § 413.65(e)(3)(ii)(B). The commenters offer this to suggest that there are instances in which a nonprofit corporation may be considered governmental.

36R. Response: The provisions of the regulation are limited to the purposes of Medicaid payment and financing, and are based on the statutory provisions governing those issues. This regulation does not affect Medicare provider-based status location requirements. States will need to apply Medicaid statutory and regulatory criteria to each individual health care provider to make determinations of governmental status for purposes of the Medicaid program.

37C. Comment: Many commenters questioned the rationale for including taxing authority, or the ability to access funding as an integral part of a government with taxing authority, as a requirement for a health care provider to qualify as a unit of government under the provisions of the regulation.

37R. Response: As discussed previously, we read the statutory definition of governmental entities to require certain common qualities, such as taxing authority, or the ability to directly access tax funding. Moreover, we believe this requirement is consistent with the overall statutory rationale. The governmental exception from provider tax and donation restrictions at section 1903(w)(6)(A) of the Act is limited to the ''use of funds where such funds are derived from State or local taxes'' (with a special provision for State university teach hospitals that receive appropriated funds which we discuss in the following response). We read the exception to be intended to permit wide flexibility in the use of tax funds, whether State or local. The limitation of this exception to the use of tax funds supports our interpretation that the reference to ''units of government'' was intended only to include entities with access to such tax funds.

As important, the purpose of the provider tax and donation restrictions in general was to prevent situations in which the health care provider contributed a non-federal share of claimed expenditures but was

essentially repaid through Medicaid or other payments. The provision at section 1903(w)(6)(A) of the Act is based on the rationale that such repayment does not occur when the health care provider uses state or local tax funding for its contribution. To give that full effect, the health care provider needs to have either taxing authority or direct access to tax funding.

38C. Comment: A number of commenters noted that the provisions of the regulation were silent on the explicit reference in section 1903(w)(6)(A) of the Act to ''funds appropriated to State university teaching hospitals'' as being permissible sources of the non-Federal share. These commenters argued that the provisions of the regulation violated Congressional intent with respect to funding arrangements involving such institutions.

38R. Response: We agree with this comment and we revised § 433.50(a)(i) and (ii) to include appropriations to State university teaching hospitals, and to define ''State university teaching hospital.'' We believe the specific provision that State university teaching hospitals could transfer funds derived from State appropriations rather than State or local tax revenues is only necessary because the statutory provisions otherwise embody the general principle that units of government must have taxing authority or direct access to tax funds. The State university teaching hospital exception makes that general principle clear, and we are revising the provisions of the regulation to reflect that exception.

39C. Comment: A number of commenters pointed out that State law typically looks beyond the presence of taxing authority to other indicia of governmental status. For example, courts may look to whether an entity enjoys sovereign immunity, whether its employees are public employees, whether it is governed by a publicly appointed board, whether it receives public funding, and whether its enabling statute declares it to be a political subdivision or a public entity. These examples were provided to suggest that CMS look beyond just taxing authority as the standard of determining whether or not an entity is a unit of government.

39R. Response: This regulation addresses governmental status for a very limited purpose and therefore we look only to criteria that are related to that purpose. For purposes of Medicaid payment and financing, the relevant characteristics of a governmental entity are those that relate to its financial organization including the source of funding and liability for its debts. These characteristics relate specifically to issues raised by the Medicaid statute. The provision of the regulation requiring that a unit of government must have access to tax revenues is consistent with the Congressional instruction contained in section 1903(w) of the Social Security Act.

As discussed previously, we read the statutory definition of governmental entities to require certain common qualities, such as taxing authority, or the ability to directly access tax funding. Moreover, we believe this requirement is consistent with the overall statutory rationale. The governmental exception from provider tax and donation restrictions at section 1903(w)(6)(A) of the Act is limited to the ''use of funds where such funds are derived from State or local taxes'' (with a special provision for State university teach hospitals that receive appropriated funds which we discuss in the following response). We read the exception to be intended to permit wide flexibility in the use of tax funds, whether State or local. The limitation of this exception to the use of tax funds supports our interpretation that the reference to ''units of government'' was intended only to include entities with access to such tax funds.

40C. Comment: A number of commenters questioned CMS' meaning with respect to a unit of government with '' taxing authority'' because this term was not defined in the regulatory text or the preamble, leaving units of government vulnerable to arbitrary or inconsistent use of this term in applying the provisions of the regulation.

40R. Response: We do not believe that this term is generally regarded as ambiguous, but we are clarifying in this response and in the regulation text at § 433.50(a)(1)(ii)(B) that we meant to refer to ''taxing authority or direct access to tax revenues.'' We believe that, in general, States have clear legal parameters setting forth those entities that have authority under their law to levy taxes. In addition, tax levies have particular treatment for purposes of federal and state taxes, and the distinction between tax levies and user fees is generally clear. We intend to defer to determinations by the State and the applicable tax authorities as to whether an entity has authority to impose taxes. The added phrase ''or direct access to tax revenues'' permits flexibility for those entities which have direct access to taxes that are imposed by a parent or related entity. For example, when a tax is imposed and collected by the State itself but is dedicated to the use of a municipality or other entity, that entity would satisfy the criteria of direct access to tax funds.

41C. Comment: A commenter asked if a legislatively created entity constitutes a ''unit of government'' if it does not have taxing authority but received government appropriations. Similarly, the commenter asked whether an entity that does not receive government appropriations, but has legislatively-established revenue raising authority or performs a legislatively-mandated function, would qualify as a unit of government.

41R. Response: In response to comments such as this one, we have modified the regulation at § 433.50 to make clear that a unit of government has either taxing authority or direct access to tax revenues. We have added the phrase ''has direct access to tax revenues'' to recognize as governmental those entities that do not have taxing authority, but do have direct access to tax revenues that are imposed by a related unit of government. By direct access, we do not mean simply that the entity receives appropriated funds or enters into a contractual arrangement with a unit of government. The entity must have the ability to receive funding as an integral part of a unit of government with taxing authority which is legally obligated to fund the health care provider's expenses, liabilities, and deficits.

42C. Comment: A commenter asked if a legislatively created entity constitutes a ''unit of government'' if it does not have taxing authority but receives both a government appropriation and other revenues through its legislatively-established revenue raising authority. If the answer is yes, the inquirer asks if there are any limits on the amount or source of funds that such an entity may spend, transfer, or contribute as the non-Federal share of an expenditure eligible for FFP.

42R. Response: The determination of governmental status is a fact-specific determination and may depend on the precise circumstances. States must apply the Federal statutory and regulatory criteria to each individual health care provider to make initial determinations of governmental status. In this instance, it is relevant whether the entity has direct access to tax revenues as an integral part of a unit of government with taxing authority which is legally obligated to fund the health care provider's expenses, liabilities, and deficits.

43C. Comment: A commenter asked if the proposed § 433.50(a)(1)(ii)(B), which speaks directly of health care providers, also includes governmental units

without taxing authority that are not health care providers.

43R. Response: This provision of the regulation is only applicable to health care providers. However, we have revised § 433.50(a)(1)(i) to address the situation of governmental units that do not have direct taxing authority, but are able to directly access funding as an integral part of a unit of government with taxing authority which is legally obligated to fund the health care provider's expenses, liabilities, and deficits, so that a contractual arrangement with the State or local government is not the primary or sole basis for the health care provider to receive tax revenues.

44C. Comment: A number of commenters inquired about whether or not appropriations made by a government for the benefit of a public or private university college of medicine, which operates a faculty practice plan, would be a permissible source of the non-Federal share of Medicaid expenditures.

44R. Response: Governmentally-operated health care providers may use appropriated tax revenues to fund the non-Federal share of Medicaid expenditures through IGTs or CPEs. Governmentally-operated health care providers are not required to demonstrate that the funds transferred or certified are, in fact, tax revenues. A governmentally-operated health care provider is always able to access tax revenue, a characteristic of which reflects a health care provider's governmental status, and helps to define eligibility to participate in IGTs and/or CPEs.

Under Public Law 102–234, Congress included an exception to a general prohibition on the receipt of voluntary contributions from health care providers by allowing units of government, including governmentally-operated health care providers, to participate in the intergovernmental transfer and certified public expenditure process. Specifically, section 1903(w)(6)(A) of the Social Security Act states:

> Notwithstanding the provisions of this subsection, the Secretary may not restrict States' use of funds where such funds are derived from State or local taxes (or funds appropriated to State university teaching hospitals) transferred from or certified by units of government within a State as the non-Federal share of expenditures under this title, regardless of whether the unit of government is also a health care provider, except as provided in section 1902(a)(2), unless the transferred funds are derived by the unit of government from donations or taxes that would not otherwise be recognized as the no-Federal share under this section.

This statutory language is very clear in its direction regarding eligibility to participate in financing the non-federal share of Medicaid payments. There is nothing in the Medicaid statute that would indicate non-governmental units could help a State finance its share of Medicaid payments, particularly in light of the significant statutory penalties States face for receiving provider-related donations as the non-Federal share of Medicaid payments (that is, non-bona fide provider-related donations).

45C. Comment: One commenter asked CMS to modify the provisions of the regulation to recognize an entity as a unit of government even though the entity may not itself have taxing authority, so long as the entity's owner has taxing authority and can transfer funds or lend its bonding authority to the entity.

45R. Response: We have modified the regulation at § 433.50 to indicate that a unit of government has either taxing authority or direct access to tax revenues. We have added the phrase ''has direct access to tax revenues'' to recognize as governmental those entities that do not have taxing authority, but do have direct access to tax revenues that are imposed by a parent or related unit of government.

For example, when a tax is imposed and collected by a State but is dedicated for use by a municipality or other entity, that entity would satisfy the criteria of direct access to tax revenues. Similarly, a county-operated hospital that is recognized in the county's budget to receive local tax subsidies via the county appropriation process, and without the need to contract for such tax revenues, would satisfy the criteria of direct access to tax revenues.

46C. Comment: Multiple commenters noted that taxing authority is not a precondition for an entity to be a unit of government. These commenters observe that while no one would doubt that a municipality is a unit of government, States frequently restrict, and may (absent State constitutional considerations) entirely suspend, municipalities' powers of taxation. Thus, these commenters contend that CMS's requirement that a governmental entity must have '' taxing authority'' in order to be considered a unit of government whose funds may be used as the state share of Medicaid expenditures is adding a requirement that fundamentally interferes with a State's own internal governmental structure. Therefore, the commenters argue that CMS should omit taxing authority as a necessary precondition for unit of government status and defer to State decisions in this matter.

46R. Response: The provisions of this regulation concerns the question of whether, in determining the amount of federal funds to which a State is entitled under the Medicaid program, transfers of funds to the State government from a Medicaid health care provider that is an entity other than the State government will be entitled to exemption from consideration as a provider tax or donation, and when expenditures of such an entity can be certified as ''public expenditures'' that constitute the non-Federal share of Medicaid expenditures. It also sets forth a consistent definition of entities that must be treated as governmental in determining the reasonableness of Medicaid payment rates. This regulation does not control how the State will organize itself. Moreover, the provisions of this regulation do not preclude entities that do not qualify as units of government from participating in the Medicaid program and contributing funds that are consistent with applicable provider tax and donation requirements.

47C. Comment: Many commenters questioned CMS's authority to define a ''unit of government'' in the manner described in this regulation. Several commenters questioned the basis for the regulation's requirement that a health care provider must have taxing authority or be an integral part of a unit of government with taxing authority. In this regard, commenters asserted their belief that Congress provided greater latitude in the statute for States and localities to determine which entities are units of government.

47R. Response: As discussed previously, we read the statutory definition of governmental entities to require certain common qualities, such as taxing authority, or the ability to directly access tax funding. Moreover, we believe this requirement is consistent with the overall statutory rationale. The governmental exception from provider tax and donation restrictions at section 1903(w)(6)(A) of the Act is limited to the ''use of funds where such funds are derived from State or local taxes'' (with a special provision for State university teach hospitals that receive appropriated funds which we discuss in the following response). An entity that has no taxing authority or direct access to tax revenues would be unable to qualify for that exception. Thus limitation of this exception to the use of tax funds supports our interpretation that the reference to ''units of government'' was intended only to include entities with access to such tax funds.

We disagree that this definition removes flexibility to finance Medicaid programs with state or local tax funds. The accounting treatment for such financing, however, may need to change to ensure program integrity consistent with the requirements of the new regulatory definition. This definition means that, for permissible financing arrangements, the entity that has taxing authority or direct access to tax funds must be the entity that either transfers the funds to the control of the State Medicaid agency, or that certifies expenditures eligible for FFP. For example, if a hospital district does not have taxing authority or direct access to tax revenues, it would not meet the requirements as a unit of government. To the extent that a county government, which had taxing authority or direct access to tax revenues, was funding Medicaid services through payments to the hospital district, however, the county could use that funding to make intergovernmental transfers, or could (with supporting documentation from the hospital) certify public expenditures based on that funding.

48C. Comment: A number of commenters noted statements in the provisions of the regulation that CMS is modifying provisions at § 433.50(a)(1) to make the definition of a unit of government consistent with section 1903(w)(7)(G) of the Act, but observed that the inclusion of '' taxing authority'' in the proposed regulatory provision is not found in section 1903(w)(7)(G) of the Act. Other commenters note that the term '' taxing authority'' is not found at section 1902(a)(2) of the Act either. Therefore, these commenters assert that the provisions of the regulation are inconsistent with the Social Security Act.

48R. Response: As discussed previously, the various statutory references to, and definitions of, governmental entities appear to reflect an understanding that such entities have common qualities, one of which is taxing authority or the ability to directly access tax funding. As noted above, we read the statutory language at section 1903(w)(7)(G) of the Act to refer to entities that have the qualities generally associated with all of the listed terms. Section 1902(a)(2) of the Act is silent on what ''local sources'' may contribute the non-federal share of Medicaid expenditures and must be read in conjunction with section 1903(w) of the Act and the overall statutory rationale. The governmental exception from provider tax and donation restrictions at section 1903(w)(6)(A) of the Act is limited to the ''use of funds where such funds are derived from State or local taxes'' (with a special provision for State university teach hospitals that receive appropriated funds which we discuss in the following response). We read the exception to be intended to permit wide flexibility in the use of tax funds, whether State or local. The limitation of this exception to the use of tax funds supports our interpretation that the reference to ''units of government'' was intended only to include entities with taxing authority or direct access to such tax funds.

As important, the purpose of the provider tax and donation restrictions in general was to prevent situations in which the State claimed that the health care provider contributed a non-federal share of claimed expenditures but the health care provider may have been actually discounting its rate or repaid through Medicaid or other payments. The provision at section 1903(w)(6)(A) of the Act was based on the rationale that this concern does not arise when the health care provider is a governmental entity using state or local tax funding for its contribution. To give that full effect, the health care provider needs to have either taxing authority or direct access to tax funding.

49C. Comment: Many commenters who questioned the basis for the requirement that a health care provider must have taxing authority or be an integral part of a unit of government with taxing authority offered characteristics that they thought should be recognized as indicative of governmental status. These characteristics include: The delegation of select governmental powers by the unit of government to the entity; criteria of governmental status used by the Internal Revenue Service (IRS); an entity's public mission; the power to issue bonds; exemption from income or property tax; governmental involvement in a health care provider's Board of Directors; government ownership of the property on which the health care provider operates; level of public oversight; provider agreements with a government to provide indigent care; rights of a health care provider to receive specific local tax revenues; creating and enabling legislative provisions; government authority to terminate an agreement for nonperformance; and financing of the health care provider's capital costs by the government.

49R. Response: This regulation addresses governmental status for a very limited purpose and therefore we look only to criteria that are related to that purpose. For purposes of Medicaid payment and financing, the relevant characteristics of a governmental entity are those that relate to its financial organization including the source of funding and liability for its debts. These characteristics relate specifically to issues raised by the Medicaid statute. The provision of the regulation requiring that a unit of government must have access to tax revenues is consistent with the Congressional instruction contained in section 1903(w) of the Social Security Act.

As discussed previously, we read the statutory definition of governmental entities to require certain common qualities, such as taxing authority, or the ability to directly access tax funding. Moreover, we believe this requirement is consistent with the overall statutory rationale. The governmental exception from provider tax and donation restrictions at section 1903(w)(6)(A) of the Act is limited to the ''use of funds where such funds are derived from State or local taxes.'' We read the exception to be intended to permit wide flexibility in the use of tax funds, whether State or local. The limitation of this exception to the use of tax funds supports our interpretation that the reference to ''units of government'' was intended only to include entities with access to such tax funds.

50C. Comment: Several commenters cited section 1903(d)(1) of the Act to argue Congressional intent with respect to the types of entities that may participate in the financing of the non-Federal share of Medicaid. This section of the statute requires States to submit quarterly reports for purposes of drawing down the Federal share, in which they must identify ''the amount appropriated or made available by the State and its political subdivisions.'' The commenters observed that this reference to political subdivisions does not include a requirement that the subdivisions have taxing authority, suggesting that the regulation's linkage to taxing authority as a requirement for recognition as a unit of government belies Congressional intent.

50R. Response: While the commenters did not cite to any definition of ''political subdivision'' of a State, the definition and criteria that we proposed for a unit of government is broader than a ''political subdivision'' of the State itself. That definition includes entities that are substantially independent of the State, but have been accorded tax authority or direct access to tax funding. If we were to restrict the ability to contribute the non-federal share only to political subdivisions of the State, that would not be consistent with the other relevant statutory provisions.

51C. Comment: Multiple commenters discussed preamble language which

says that tax revenue that is contractually obligated between a governmental entity and a health care provider to provide indigent care is not considered a permissible source of the non-Federal share of funding for purposes of Medicaid payments, and argued that this restriction violates Section 1903(w)(6) of the Act, which states that the Secretary may not restrict any transfers or certifications ''where such funds are derived from State or local taxes.'' A number of commenters disagreed with this same language, claiming that CMS has no authority to limit how a health care provider and unit of government use tax revenue to best achieve the objective of providing indigent care.

Other commenters recommended that CMS clarify that it will not view the transfer of taxpayer funding for a specific health care provider as an indirect provider donation and allow those appropriations to be considered IGTs. The commenters pointed to language in the preamble that stipulates that ''health care providers that forego tax revenue that has been contractually obligated for the provision of health care services to the indigent * * * are making provider-related donations.'' A commenter also questioned whether the following situation with respect to appropriated funds would be considered an indirect provider donation or an eligible IGT: a county that is statutorily required to provide a fixed appropriation to a private hospital, and the statute expressly allows that appropriation to be used as IGT. The commenter provided another scenario and questioned if this would quality as an appropriate IGT: a formerly public hospital received a State appropriation, which it currently uses as an IGT.

51R. Response: Section 1903(w)(6)(A) of the Medicaid statute provides that only governmental units may transfer or certify funds based on governmental status, and separately indicates that the funds must be derived from state or local tax revenues. A non-governmental provider cannot transfer or certify funds (except consistent with provider donation rules) under any circumstances. If a non-governmental provider receives appropriated funds or other payments from a unit of government, that unit of government may certify any expenditures made to that non-governmental provider that would qualify for FFP as an expenditure under the State plan. Tax revenue that has been contractually or otherwise obligated to a non-governmentally-operated health care provider for non-Medicaid services is not a permissible source of the non-Federal share of Medicaid payments under the statute. If a health care provider would forego revenues from that governmental unit, it would be a donation from that non-governmental provider. A Medicaid payment that can be linked to a provider-related donation renders such donation non-bona-fide and thus an impermissible source of the non-Federal share. This is consistent with section 1903(w)(6)(A) of the Act, which permits transferred funds from a local government to the State to be used for purposes of financing the non-Federal share of Medicaid payments, ''unless the transferred funds are derived by the unit of government from donations or taxes that would not otherwise be recognized as the non-Federal share.''

52C. Comment: A number of commenters noted the regulation's preamble statement that in order for tax funding to be eligible as the non-Federal share, it cannot be committed or earmarked for non-Medicaid activities. One such commenter stated that State or local appropriations are not precisely related to Medicaid activities and that the applicable allotments of tax revenues are committed for defined purposes, such as public assistance programs that include ''Medicaid and other activities'' or ''Medicaid and other needy individuals.'' This commenter observed that the Departmental Appeals Board recognizes the difference between expenditures for these items and the accounting entries that determine Medicaid expenditures eligible for FFP. Governmental appropriations are routinely committed or earmarked for the former, while FFP is applicable only to the latter. Another commenter feared that this preamble language was ambiguous because government funding can be ''earmarked'' for a purpose other than Medicaid that is actually consistent with the use of funds for Medicaid. Therefore, these commenters believe that this provision of the regulation requires clarification and more explanation about how it would be applied.

52R. Response: In response to this comment, we clarify that our intent was that we would not recognize as units of government qualified to contribute non-federal share those entities with access to tax funds that were committed or earmarked solely for non-Medicaid activities (or to recognize contributions in excess of the amount of funding available for Medicaid activities). Our concern was to preclude arrangements where entities whose access to tax funding was limited to non-Medicaid activities ''borrow'' those funds to contribute the non-federal share of Medicaid expenditures and then ''repay'' those funds from Medicaid reimbursements (with the result that the remaining Medicaid funding is federal only). We did not intend to suggest that it would be a problem if Medicaid was one of several permissible uses for the tax funding.

53C. Comment: One commenter disagreed with the part of the regulation which says that tax revenue that is contractually obligated between a governmental entity and a health care provider to provide indigent care is not considered a permissible source of the non-Federal share of funding for purposes of Medicaid payments. The commenter indicated that CMS should permit funding under an indigent care contract to be transferred by the local government to the State to draw down Federal matching funds for Medicaid payments.

53R. Response: Local government tax dollars that are not contractually committed for the purpose of indigent care services or any other non-Medicaid activity can be directly transferred by the local government to a State as the non-Federal share of Medicaid payments. But when a non-governmental provider forgoes payment to which it is contractually entitled from a local government, it would be making a provider donation.

54C. Comment: One commenter stated their understanding of section 1903(w)(6)(A) of the Act to indicate that as long as the funds used by a governmental entity for the non-federal share of Medicaid payments issue from or originate from local taxes, they would fall under the type of funds that may not be restricted by CMS. The commenter disagreed with CMS' position in the provision of the regulation that the non-federal share of Medicaid payments must be funded by taxes. The commenter requested that CMS clarify that *all* of an entity's revenues, whether received as direct appropriations from its local taxing authority or derived from such appropriations, which help to pay for capital improvements, employees and other costs, are public funds and can be used as the non-federal share of Medicaid payments.

54R. Response: We disagree. Section 1903(w)(6)(A) of the Act protects IGTs and CPEs only when ''derived from State or local taxes (or funds appropriated to a State university teaching hospital).'' This statutory clause would not be necessary if any governmental entity revenues could be used for protected transactions. When funds are received by a health care provider in the course of its normal operations, those funds are not ''derived from State or local taxes'' unless they

are tax funds or are funds appropriated by a government entity from tax revenues and paid for Medicaid services at the health care provider. Funds appropriated from tax revenues and paid for non-Medicaid services at the health care provider lose their characteristic as ''derived from State or local taxes'' and, to the extent unexpended on the designated non-Medicaid services, would be profits derived from the provision of those services.

Such funds could not be used to contribute the non-Federal share of Medicaid expenditures because they are derived from the operations of the health care provider, rather than from State or local tax revenues. We recognize that funds received for specific costs, such as capital improvements or employee costs, may in part fund the costs of Medicaid services. These funds could be used to fund the non-Federal share to the extent that those specific costs may be properly allocated to Medicaid services, in accordance with the governmentally-operated health care provider's approved cost allocation plan. We also recognize that funds from different sources can be commingled in health care provider accounts. As a result, in this regulation we are not requiring that governmentally-operated health care providers trace funding precisely. We are requiring that, to qualify as a unit of government, the entity must have taxing authority or direct access to State or local tax funds in at least the amount of the IGT or CPE; and we are requiring that a health care provider retain the full amount of the total computable payment claimed by the State under the Medicaid State plan.

B. ''Tool to Evaluate the Governmental Status of Providers'' Form

55C. Comment: Several commenters noted that the ''Tool to Evaluate the Governmental Status of Providers'' form does not include an indication of the final result on the form and recommended that the form include such a final determination.

55R. Response: We agree and we have revised the form to include an indication of the State's determination of a health care provider's governmental status. * * *

56C. Comment: A few commenters noted that the ''Tool to Evaluate the Governmental Status of Providers'' form would need to be completed and submitted by all purportedly governmental providers in America within three months of the effective date of the regulation and suggested that CMS will not have the resources to review all these submissions and determine whether or not each health care provider is a ''unit of government'' in a timely manner. Concern was expressed that delays by CMS in reaching a decision about whether or not entities are governmental may impede provider reimbursements.

56R. Response: In this final rule, we are providing that States must apply the statutory and regulatory criteria to each individual health care provider to make initial determinations of governmental status. As we indicated in the proposed rule, we have developed a ''Tool to Evaluate the Governmental Status of Health Care Providers.'' In response to comments on this rule, we have modified that form to allow States to indicate their initial determination of a health care provider's governmental status.

States must apply the statutory and regulatory criteria to each individual health care provider to make initial determinations of governmental status. We have modified the ''Tool to Evaluate the Governmental Status of Health Care Providers'' to allow States to indicate their initial determination of a health care provider's governmental status.

States will be required to maintain these determinations on file and will be required to submit these forms to CMS upon request, in connection with CMS review of Medicaid institutional and non-institutional reimbursement State plan amendments involving governmental providers and with Medicaid or SCHIP financial management reviews. In addition, we intend to request, under our general authority to require supporting documentation for claimed expenditures, and the existing regulatory authority at 42 CFR § 431.16, that States submit a complete list of governmentally-operated health care providers to the Associate Regional Administrator for Medicaid of each State's respective CMS Regional Office with the first quarterly expenditure report due after 90 days of the effective date of the regulation.

CMS is not requiring States to complete the ''Tool to Evaluate the Governmental Status of Health care Providers'' form for each Indian tribe and tribal organization within the State, because the unique criteria for determining the governmental status of tribes and tribal organizations makes the tool inapplicable to these entities. However, CMS will require each State to identify the qualifying tribes and tribal organizations (per the criteria at § 433.50) in any list of governmentally-operated health care providers submitted to CMS. Although tribal facilities are exempt from the Medicaid cost limit, the inclusion of tribes and tribal organizations in this list will comprehensively identify the universe of entities that have been determined by the State as eligible to participate in financing the non-Federal share of Medicaid payments.

57C. Comment: A number of commenters asked for more details concerning CMS actions upon receipt of the ''Tool to Evaluate the Governmental Status of Providers'' form. Specifically, the commenters wanted more information on the timeframes for CMS decisions; how CMS will notify States of a determination; means for amending information previously provided; and avenues for appeal when States, local governments, or health care providers disagree with the decision as to whether or not a health care provider is found to be a unit of government.

57R. Response: As discussed above, in response to comments, we have provided in the final rule that States must apply the statutory and regulatory criteria to each individual health care provider to make initial determinations of governmental status. We have modified the ''Tool to Evaluate the Governmental Status of Health Care Providers'' to allow States to indicate their initial determination of a health care provider's governmental status. States may develop reasonable determination, notice and appeal processes for health care providers affected by State determinations as they deem appropriate. If CMS disagrees with a State's initial determination of governmental status, CMS intends to request a timely change in the State's determination prior to pursuing any other measures including, but not limited to, denial of Medicaid reimbursement SPAs and/or disallowances of claims for Federal financial participation. States can appeal such actions through existing appeal processes.

58C. Comment: Multiple commenters commented on the administrative burden associated with completion of the ''Tool to Evaluate the Governmental Status of Providers'' form. These commenters stated that for some health care providers, completion of the form may require extensive legal research and analysis because of the potential for complicated legal implications. These commenters contend that the burden associated with completing the form is disproportionate to the form's utility, especially since it is not clear how CMS will ultimately use the form to determine governmental status.

58R. Response: The ''Tool to Evaluate the Governmental Status of Health Care

Providers'' is designed to guide State decision making in applying the statutory and regulatory criteria regarding the definition of a unit of government. The provisions of the regulation were designed to ensure consistent application of the Federal statutory instructions regarding the definition of a unit of government. CMS recognizes that for purposes of Medicaid State financing legal and financial arrangements between health care providers and units of government vary on a case by case basis. We have developed standardized and impartial regulatory criteria based upon the Federal statute, which States must apply on a consistent basis to each health care provider within the State.

CMS does not believe the information required in the form requires the extensive, legal research and analysis as the commenters suggest. CMS has the responsibility to ensure that the State's initial determinations are consistent with the Federal statutory and regulatory criteria and reserves the right to take any appropriate action including, but not limited to denial of Medicaid reimbursement State plan amendments and/or disallowances of claims for Federal financial participation, in the event of noncompliance with any provision of this regulation. States can appeal such actions through existing appeals processes.

59C. Comment: One commenter recommended that instead of using the form, CMS require certifications and assurances from health care providers and State and local governments regarding their governmental status.

59R. Response: We do not believe that certifications and assurances are adequate in determining compliance with Federal statutory and regulatory provisions regarding the unit of government definition.

60C. Comment: One commenter argued that the Federal government should fund 100% of all costs associated with any mandate involving the completion of the questionnaire or submission of such information to CMS.

60R. Response: Each State is responsible for the proper and efficient administration of its Medicaid program. Expenses incurred for administration of the Medicaid program are eligible for Federal matching funds at the regular 50 percent administrative matching rate.

61C. Comment: A number of commenters asserted that the ''Tool to Evaluate the Governmental Status of Providers'' form is unnecessary because CMS should defer to States and local governments to define which entities are units of government for purposes of Medicaid financing, based on arguments such as statutory authority, principles of federalism, and marketplace incentives.

61R. Response: The ''Tool to Evaluate the Governmental Status of Health Care Providers'' is designed to guide State decision making in applying the statutory and regulatory criteria regarding the definition of a unit of government. The provisions of the regulation were designed to ensure consistent application of the Federal statutory instructions regarding the definition of a unit of government for purposes of Medicaid reimbursement and State financing. CMS recognizes that States play a major role in the administration of the Medicaid program and that legal and financial arrangements between health care providers and units of government vary on a case by case basis. We have developed standardized and impartial regulatory criteria based upon Federal statute that States must apply on a consistent basis to each health care provider within the State.

We considered the possibility of deferring to State determinations but we concluded that it was important for effective oversight review to receive standardized information and establish a clear, uniform and enforceable standard.

We believe the form will be useful to States which will have to apply the statutory and regulatory criteria to each individual health care provider to make initial determinations of governmental status. CMS has the responsibility to ensure that the State's initial determinations are consistent with the Federal statutory and regulatory criteria and reserves the right to take any appropriate action including, but not limited to, denial of Medicaid reimbursement State plan amendments and/or disallowances of claims for Federal financial participation, in the event of noncompliance with any provision of this regulation.

62C. Comment: One commenter asked CMS for more written guidance on the use of this form when the final regulation is published. Specifically, the commenter asked who is responsible for completing the form and what, if any, supporting documentation is required. Moreover, the commenter noticed that the form does not, in its current format, require an official signature.

62R. Response: States must apply the statutory and regulatory criteria to each individual health care provider to make initial determinations of governmental status. We have modified the ''Tool to Evaluate the Governmental Status of Health Care Providers'' to require that an appropriate State official sign the State's initial determination regarding the governmental status of a health care provider. The State official that will be responsible for signing the form will be a decision of the State. Further, the State will determine what supporting documentation may be necessary on a case-by-case basis in support of its initial determination of a health care provider's governmental status.

63C. Comment: A number of commenters noted that the provisions of the regulation suggest that a health care provider may be considered a unit of government if the health care provider appears on the unit of government's consolidated annual financial report. Likewise, the commenters observed, the provisions of the regulation mention a unit of government's liability for a health care provider's expenses, liabilities, and deficits in order for the health care provider to be considered a unit of government. However, it is not clear that responses to questions presented on the tool will lead to a final determination as to whether or not a particular entity is considered a unit of government as per the provisions of the regulation. Therefore, the commenters find a ''disconnect'' between the provisions of the regulation and the ''Tool to Evaluate the Governmental Status of Providers'' form. This disconnect was viewed as creating problems when States attempt to evaluate whether or not they can rely upon IGTs or CPEs from a particular health care provider in the future, and it may also contribute to unnecessary and protracted litigation of an apparently arbitrary determination by CMS about the governmental status of a health care provider.

63R. Response: States must apply the statutory and regulatory criteria to each individual health care provider to make initial determinations of governmental status. We designed the ''Tool to Evaluate the Governmental Status of Health Care Providers'' to set up a process to collect and maintain information necessary for such determinations. We believe the form fully reflects the statutory and regulatory criteria necessary for States to make initial determinations of governmental status.

We have modified the form to allow States to indicate their initial determination of a health care provider's governmental status. We understand that there will be challenges in implementing the determination process. As States apply the statutory and regulatory criteria, CMS will exercise oversight review and will issue guidance on the implementation of the

statutory and regulatory criteria if warranted.

64C. Comment: One commenter asked CMS to provide instructions and/or direction for the preparation and submission of the form to assist the State in analyzing the complex financial and organizational relationships which exist in the varied governmental units within the State. The commenter suggests that CMS provide the criteria and direction for the States to determine that a health care provider is unit of government with the provision that CMS may review or audit the State's determination.

64R. Response: The ''Tool to Evaluate the Governmental Status of Health Care Providers'' is designed to guide State decision making in applying the statutory and regulatory criteria regarding the definition of a unit of government. The provisions of the regulation were designed to ensure consistent application of the Federal statutory instructions regarding the definition of a unit of government. CMS recognizes that for purposes of Medicaid State financing legal and financial arrangements between health care providers and units of government vary on a case by case basis. We have developed standardized and impartial regulatory criteria based upon the Federal statute, which States must apply on a consistent basis to each health care provider within the State. CMS believes the form fully reflects the statutory and regulatory criteria necessary for States to make initial determinations of governmental status.

We understand that there will be challenges in implementing the determination process. As States apply the statutory and regulatory criteria, CMS will exercise oversight review and will issue guidance on the implementation of the statutory and regulatory criteria if warranted.

65C. Comment: Multiple commenters inquired specifically about the State Medicaid agency's responsibility for identifying a health care provider as governmentally operated. If the provider has not identified itself as a governmental health care provider, must the State Medicaid agency establish procedures to make such an identification?

65R. Response: It is the State's responsibility to make initial determinations regarding the governmental status of each health care provider. The ''Tool to Evaluate the Governmental Status of Providers'' form has been modified to reflect the State's initial determination, and a signature line to be signed by an appropriate State official has been added. States may develop procedures to facilitate the identification of a governmentally-operated health care provider and include appeals processes for health care providers affected by State determinations.

66C. Comment: One commenter observed that CMS has collected information about the governmental status of health care providers in the past and stated that based on information previously obtained by CMS, the ''Tool to Evaluate the Governmental Status of Providers'' form is unnecessary and wasteful.

66R. Response: It is unclear as to what information was previously provided to CMS regarding governmental status of health care providers. The ''Tool to Evaluate the Governmental Status of Health Care Providers'' is designed to guide State decision making in applying the statutory and regulatory criteria regarding the definition of a unit of government. The provisions of the regulation were designed to ensure consistent application of the Federal statutory instructions regarding the definition of a unit of government. We have developed standardized and impartial regulatory criteria based upon Federal statute that States must apply on a consistent basis to each health care provider within the State.

CMS has the responsibility to ensure that the initial determinations are consistent with the Federal statutory and regulatory criteria and reserves the right to take any appropriate action including, but not limited to, denial of Medicaid reimbursement State plan amendments and/or disallowances of claims for Federal financial participation, in the event of noncompliance with any provision of this regulation.

67C. Comment: One commenter noted that the questionnaire ''Tool to Evaluate the Governmental Status of Providers'' form would need to be completed and submitted by all school districts in America within three months of the effective date of the regulation and suggested that CMS will not have the resources to review all these submissions and determine whether or not each school district is a ''unit of government'' in a timely manner. The commenter believes it is obvious that school districts are governmental and should therefore be exempt from the requirement to complete the questionnaire.

67R. Response: States must apply the statutory and regulatory criteria to each individual health care provider to make initial determinations of governmental status. We have modified the ''Tool to Evaluate the Governmental Status of Health Care Providers'' to allow States to indicate their initial determination of a health care provider's governmental status.

States will be required to maintain these determinations on file and will be required to submit these forms to CMS upon request, in connection with CMS review of Medicaid institutional and non-institutional reimbursement State plan amendments involving governmental providers and with Medicaid or SCHIP financial management reviews.

C. Funds From Units of Government as the State Share of Financial Participation (§ 433.51)

1. Intergovernmental Transfers (IGTs)

68C. Comment: One commenter suggested that Congress intended that section 1903(w)(7)(G), which defines the term ''unit of local government,'' was only applicable to section 1903(w)(1)(A) of the Act, and was not applicable to section 1903(w)(6)(A) of the Act. The writer noted the absence of the word ''local'' in section 1903(w)(6)(A) and suggested that such an omission was deliberate because Congress meant something different in this Section. Specifically, the commenter claimed that Congress used the narrower term ''unit of local government'' to define those government entities subject to the prohibition on provider donations and taxes (1903(w)(1)(A)), but recognized that other government entities may permissibly make IGTs, and thus purposely used the broader and different term ''unit of government'' in the IGT section of the statute (1903(w)(6)(A)). Therefore, the writer suggests, CMS is misguided in applying the statute's ''unit of local government'' reference to section 1903(w)(6)(A) of the Act.

68R. Response: As discussed previously, we are attempting to interpret the statutory references and definitions of governmental entities to ensure uniformity and consistency. We agree that we could have adopted different operational definitions for different purposes, but we concluded that such an approach would be confusing and was unnecessary. Our reading requires certain common qualities, one of which is taxing authority, or the ability to directly access tax funding. As noted above, we read the statutory language at section 1903(w)(7)(G) of the Act to refer to entities that have the qualities generally associated with the specifically identified listed terms. One of those qualities, which is referenced in the governmental exception at section

1903(w)(6)(A) of the Act, is taxing authority or the ability to directly access tax funding. Even though sections 1903(w)(6)(A) and 1903(w)(7)(G) of the Act are not directly binding for all statutory purposes, we sought a definition that would be consistent with readings of both statutory provisions.

69C. Comment: One commenter quoted prior CMS statements from regulations published in 2001 and 2002, wherein CMS did not take regulatory action with respect to intergovernmental transfers, suggesting that CMS is now not only contradicting itself but also imposing restrictions on IGTs that Congress never intended.

69R. Response: The provisions of this regulation continue to protect the use of IGTs; the regulation merely sets out in clear terms the circumstances in which the provisions of section 1903(w)(6)(A) of the Act provides that an IGT from a governmentally-operated health care provider would not trigger review as a provider tax or donation. This regulation supersedes prior CMS statements on the issue and would provide important clarity in an area that has been the subject of much confusion. Furthermore, we disagree with the commenters' contention concerning congressional intent. In section 1903(w)(6)(A) of the Act, the Medicaid statute clearly protects only IGTs or certified public expenditures that are ''derived from State or local taxes (or funds appropriated to State university teaching hospitals) transferred or certified by units of government within a state.'' To the extent that the provisions of this regulation impose restrictions on IGTs, such restrictions are consistent with this statutory provision and serve to clarify and give meaning to the statutory language.

70C. Comment: Many commenters stated that the provisions of the regulation require sources of all IGTs must be state or local taxes and that such a restriction on IGT funding is inconsistent with the Medicaid statute. These commenters noted that governments derive their funding from a variety of sources, not just tax proceeds, and such funds are no less governmental due to their source. Some of the non-tax sources of governmental revenue that were cited include patient care revenues from other third party payers, penalties, fees, grants, earned interest, library fines, restaurant inspection fees, vending machine sales, traffic fines, unreserved general fund balances, sale or lease of public resources, legal settlements and judgments, revenue from bond issuances, tobacco settlement funds, and gifts. These commenters suggested that CMS should allow all public funding, regardless of source, to be used as the non-Federal share of Medicaid expenditures. A number of commenters cited Section 1902(a)(2) of the Act, which permits up to 60 percent of the non-Federal share to come from ''local sources,'' without further restriction. This citation was given to counter a perceived CMS position that the provisions of the regulation require that the sources of all IGTs must be state or local taxes. Several other commenters suggested that CMS should allow all public funding, regardless of source, to be used as the non-Federal share of Medicaid expenditures, and that CMS has no statutory authority to limit the sources of transferred funds to tax revenue only.

70R. Response: Provisions regarding non-federal share financing were established in recognition of the Federal Medicaid statute at section 1903(w), which places severe statutory restriction on States' receipt of funds from health care providers to fund Medicaid payments. (see Public Law 102–234, section 2, *Prohibition on Use of Voluntary Contributions,* and Limitation on the Use of Provider-Specific Taxes *to Obtain Financial Participation under Medicaid.*''). Under Public Law 102–234, the Congress included an exception to a general prohibition on the receipt of voluntary contributions from health care providers by allowing units of government, including governmentally-operated health care providers, to participate in financing of the non-Federal share via intergovernmental transfers and certified public expenditures. Specifically, section 1903(w)(6)(A) of the Social Security Act states:

> Notwithstanding the provisions of this subsection, the Secretary may not restrict States' use of funds where such funds are derived from State or local taxes (or funds appropriated to State university teaching hospitals) transferred from or certified by units of government within a State as the non-Federal share of expenditures under this title, regardless of whether the unit of government is also a health care provider, except as provided in section 1902(a)(2), unless the transferred funds are derived by the unit of government from donations or taxes that would not otherwise be recognized as the no-Federal share under this section.

This statutory language allows funding derived from State or local taxes to be used for purposes of financing the non-Federal share of Medicaid payments. CMS recognizes that units of government that are not health care providers may collect revenue from a variety of sources (including fees, grants, earned interest, fines, sale or lease of public resources, legal settlements and judgments, revenue from bond issuances, tobacco settlement funds) that are ultimately deposited into the government's general fund, which is used to finance the government's operations. We find such general fund revenues to be acceptable sources of financing the non-Federal share of Medicaid payments, as long as the general fund does not derive any of its revenue from impermissible sources (such as, ''recycled'' Medicaid payments, Federal grants precluded from use as State match, impermissible taxes, non-bona fide provider-related donations).

Governmentally-operated health care providers may maintain accounts separate from the general fund to finance the operations of the governmentally-operated health care provider. The governmentally-operated health care provider's account may include patient care revenues from other third party payers and other revenues similar to those listed above. Such revenues would also be acceptable sources of financing the non-Federal share of Medicaid payments, as long as the governmentally-operated health care provider's operating account does not derive any of its revenue from impermissible sources (such as, ''recycled'' Medicaid payments, Federal grants precluded from use as State match, impermissible taxes, non-bona fide provider-related donations).

As previously explained, governmentally-operated health care providers are not required to demonstrate that funds transferred are, in fact, tax revenues. A governmentally-operated health care provider is always able to access tax revenue, a characteristic of which reflects a health care provider's governmental status, and helps to define eligibility to participate in IGTs.

71C. Comment: A number of commenters asked CMS to clarify that intragovernmental transfers (transfers within a unit of government, such as a transfer from the State's mental health agency to the State Medicaid Agency) are not considered ''intergovernmental transfers'' for purposes of § 433.51.

71R. Response: Neither the Medicaid statute nor Federal regulation uses the term ''intragovernmental transfer.'' For purposes of the Medicaid statute, a transfer of funding between any governmental entity within a State to the State Medicaid Agency is considered an intergovernmental transfer, irrespective of whether or not those entities are operated by the same unit of government (e.g., a State Department of Mental Health

transferring funds to a State Medicaid agency).

72C. Comment: One commenter recommended that CMS permit IGTs from units of government in other States (like governmentally operated border hospitals) to be considered permissible sources of financing the non-Federal share. The commenter argues that it is illogical that States are required to reimburse such out-of-state health care providers the same as in-state health care providers but cannot rely upon those out-of-state governmental health care providers for assistance with financing.

72R. Response: A governmentally-operated health care provider in one State is not under the governmental control of another State. Therefore, funds transferred by a governmentally-operated health care provider to a State Medicaid Agency in another State are considered provider-related donations. See Georgia Department of Community Health, DAB No. 1973 (2005).

73C. Comment: One commenter asked that the regulation explicitly state the local dollars will be considered valid IGTs if they originated at a unit of government, regardless of the entity that actually transfers the payment to the State. This commenter specifically mentions Medicaid Behavioral Health Plans, which receive payments from local governments and, in turn, forward those payments to the State Medicaid Agency as matching funds to pay for the non-Federal share. Another commenter requested that CMS allow any payments made to health care providers by governmental entities responsible for providing health care services to be used as IGTs.

73R. Response: Any time state or local tax dollars are used to make ''payments'' for services to health care providers, such payments are considered revenues of the health care provider and are no longer considered State or local tax dollars. Governmentally-operated health care providers may participate in intergovernmental transfers (IGTs) and use operating revenues to make such transfers. Non-governmentally-operated health care providers cannot participate in IGTs, and contributions of their operating revenue constitutes a provider-related donation. A Medicaid payment that can be linked to a provider-related donation renders such donation non-bona fide and thus an impermissible source of the non-Federal share.

74C. Comment: Several commenters noted past abuses involving intergovernmental transfers and expressed support for CMS efforts to end such abusive practices. However, the commenters contended that the provisions of the regulation reach too far, beyond the termination of abusive IGTs, and have the impact of drawing millions of Federal funds away from health care providers and States that were not ''recycling'' Federal funds through IGTs.

74R. Response: The provision of the regulation that addresses a unit of government codifies the existing statutory criteria for a unit of government that can participate in financing the non-federal share of Medicaid expenditures. This codification of existing Federal statute was established in an effort to assist States in identifying the universe of governmentally-operated health care providers that could receive Medicaid revenues up to the full cost of providing services to Medicaid individuals and clarifies which types of health care providers can participate in financing of the non-Federal share of Medicaid payments.

A health care provider that is not recognized as governmentally-operated under the Federal statutory and regulatory criteria would not be affected by the cost limitation on Medicaid payments. Therefore, such health care providers may receive Medicaid payments up to the applicable regulatory upper payment limit, to the extent States use permissible sources of non-federal share funding to make such payments. Furthermore, a health care provider that is not recognized as governmentally-operated by a State when applying the statutory criteria would not be subjected to non-federal share obligations under a State's Medicaid program. For any health care provider previously obligated to fund certain Medicaid payments, total Medicaid revenues to that facility can be sustained through alternative permissible sources of non-federal share funding. Health care providers determined to be ineligible to participate in the State financing of Medicaid payments can actually realize greater net Medicaid revenues if State or local government funding sources are utilized to fund non-federal share obligations to Medicaid payments that may have been historically financed by non-governmentally-operated health care providers.

75C. Comment: One commenter requested that CMS allow the use of IGTs to finance payments for categorical Medicaid payments. The commenter also requested that CMS confirm the use of IGTs to finance Medicaid payments approved in the State plan.

75R. Response: Intergovernmental transfers, consistent with statutory and regulatory provisions, are an allowable source of Medicaid financing for any payment authorized under the Medicaid State plan.

76C. Comment: One commenter noted that it will be administratively burdensome to have all school districts within the state demonstrate that their intergovernmental transfers are paid from tax revenues. In addition, the commenter states that the process of collecting the State match from each school district before the district's claims are paid cannot be implemented without significant changes to the State's MMIS, which would be a massive undertaking.

76R. Response: CMS recognizes that units of government may collect revenue from a variety of sources (including fees, grants, earned interest, fines, sale or lease of public resources, legal settlements and judgments, revenue from bond issuances, tobacco settlement funds) that are ultimately deposited into the government's general fund, which is used to finance the government's operations. Generally, we find such revenues to be acceptable sources of financing the non-Federal share of Medicaid payments, as long as the unit of government does not attempt to finance Medicaid payments using revenue from impermissible sources (such as, ''recycled'' Medicaid payments, Federal grants precluded from use as State match, impermissible taxes, non-bona fide provider-related donations).

Funds may be transferred by units of government that are not health care providers to the State Medicaid agency either before or after the payment to the provider is made, provided that the requirements of § 447.207 are satisfied. A principal concern in evaluating compliance with § 447.207 will be the determination as to whether or not the funding obligation to the non-Federal share of Medicaid payments has been fully satisfied by the State or local government. IGTs from a local or other State Agency unit of government's general fund may be considered a permissible source of the non-Federal share of Medicaid payments when: (1) Monies from the general fund are transferred to the State Medicaid agency; (2) such monies are used to fund the non-Federal share of Medicaid payments to the governmentally-operated health care provider; (3) the health care provider deposits such Medicaid payments into its operating account (a governmentally-operated health care provider will always maintain an operating account that is separate from the general fund managed by the corresponding unit of

government); and (4) no portion of Medicaid payments deposited into the operating account is sent back to the general fund to replenish the loss of funds resulting from the IGT. These conditions would demonstrate that the burden of the non-Federal share of the Medicaid payment was satisfied by the local government or other State Agency.

Governmentally-operated health care providers may *only* transfer prior to receiving a Medicaid payment to ensure funds were actually available to the governmentally-operated health care provider to satisfy the non-Federal share obligation to the Medicaid payment it receives. To permit non-Federal share transfer obligations made by a governmentally-operated health care provider after the Medicaid payment is received would allow a Medicaid Agency to ''loan'' the non-Federal share obligation to the governmentally-operated health care provider. Upon receipt of the Medicaid payment, the governmentally-operated health care provider would be able to ''return'' the ''loan'' to the Medicaid Agency via its non-Federal share transfer obligation. The end result of such a post-payment IGT would be that a State is able to direct Federal matching funds into a governmentally-operated health care provider without any unit of government satisfying the non-Federal share obligation. The State could then use the same funds to make additional Medicaid payments and attract new Federal matching funds.

2. Certified Public Expenditures (CPE)

77C. Comment: Two commenters expressed that ''only hospitals that meet the new definition of public hospital and are reimbursed on a cost basis would be eligible to use CPEs to help states fund their programs,'' claiming that this would result in fewer dollars available to pay for care for the nation's most vulnerable people.

77R. Response: There is no new definition of a public hospital under the provisions of this regulation. The Federal Medicaid statute does not include a term nor discussion that references a ''public'' health care provider for purposes of State Medicaid financing. The Federal Medicaid statute at section 1903(w) of the Act places severe statutory restriction on States' receipt of funds from health care providers to fund Medicaid payments. This section of the statute includes an exception to the general prohibition on the receipt of voluntary contributions from health care providers by allowing units of government, including governmentally-operated health care providers, to participate in the certified public expenditure process.

The provision of the regulation regarding certified public expenditures is a clarification to existing Federal statutory instruction at 1903(w)(6)(A). Consistent with this explicit statutory instruction, a certified public expenditure means that State or local tax dollars were used to satisfy the cost of serving Medicaid individuals (and the cost of providing inpatient and outpatient hospital services to the uninsured for purposes of Medicaid DSH payments).

Under the provisions of the regulation, all health care providers maintain some level of ability to participate in the certified public expenditure (CPE) process. Governmentally-operated health care providers are able to certify their costs without having to demonstrate that State or local tax dollars were used to provide Medicaid services. This policy is based on the fact that governmentally-operated health care providers always have the ability to directly access State and/or local tax dollars as an integral component of State or local government. Governmentally-operated health care providers need only produce cost documentation via national, standardized cost reporting to receive Federal matching funds as a percentage of such allowable Medicaid (and DSH) costs.

Non-governmentally-operated health care providers may also produce cost documentation to support the costs of providing services to Medicaid individuals (and certain uninsured costs for purposes of Medicaid DSH payments). However, in order to maintain consistency with the Federal statutory instruction governing CPEs, a State or local government must actually certify that tax dollars were provided to the non-governmentally-operated health care provider. Federal matching funds will be available as a percentage of the allowable Medicaid costs incurred by the non-governmentally-operated health care provider up to the level of such State and/or local tax support.

78C. Comment: A number of commenters opined that when a public entity is contractually obligated to reimburse private faculty physicians, which are in turn obligated to provide services to the public entity's patients, those public payments should qualify as CPEs. However, the commenters stated a belief that it was unclear what, if any, expenditures by public entities qualify as CPEs, and that the required documentation and approval process for such CPEs appear arbitrary. The commenters thus recommended that CMS should defer to the services and payment methodologies approved in the Medicaid State Plan and that however the public entity pays the health care provider should qualify as a CPE.

78R. Response: The Federal Medicaid statute does not include a term nor discussion that references a ''public'' health care provider for purposes of State Medicaid financing. The Federal Medicaid statute at section 1903(w) places severe statutory restriction on States' receipt of funds from health care providers to fund Medicaid payments. This section of the statute includes an exception to the general prohibition on the receipt of voluntary contributions from health care providers by allowing units of government, including governmentally-operated health care providers, to participate in the certified public expenditure process.

The options available to a unit of government for purposes of compliance with the CPE provisions of the regulation depend on whether or not the unit of government is the provider of the service. A governmental entity that is not a health care provider and that pays for a covered Medicaid service furnished by a health care provider (whether governmentally-operated or not) can certify its actual expenditure in an amount equal to the Medicaid State plan rate (or the approved provisions of a waiver or demonstration, if applicable) for the service. In this case, the CPE would represent the expenditure by the governmental unit to the service provider on behalf of the State Medicaid agency(and would not necessarily be related to the actual cost to the health care provider for providing the service).

If the unit of government is the health care provider, then it may generate a CPE from its own costs if the Medicaid State plan (or the approved provisions of a waiver or demonstration, if applicable) contains cost reimbursement methodology. If this is the case, the governmentally-operated health care provider may certify the costs that it actually incurred that would be reimbursed under the Medicaid State plan. If the Medicaid State plan does not contain an actual cost reimbursement methodology, then the governmentally-operated health care provider may not use a CPE because it would not be able to establish an expenditure under the authority of the Medicaid State plan. This is consistent with the requirements of 45 CFR 95.13, where there was no cost incurred that would be recognized under the Medicaid State plan. A governmentally-operated health care provider cannot establish an expenditure under the Medicaid State

plan by asserting that it would pay itself the Medicaid State plan rate.

79C. Comment: Several commenters stated that they thought the burden associated with documenting certified public expenditures under the proposed regulation is excessive. This view was emphasized for expenditures eligible for FFP which are not currently subject to cost reporting.

79R. Response: The documentation requirements for CPEs are necessary and appropriate. We have examined CPE arrangements in many States that include various service categories within the Medicaid program. We note that currently there are a variety of practices used by State and local governments in submitting a CPE as the basis of matching FFP for the provision of Medicaid services with little to no State oversight. Different practices often make it difficult to (1) Align claimed expenditures with specific services covered under the State plan or identifiable administrative activities; (2) properly identify the actual cost to the governmental entity of providing services to Medicaid individuals or performing administrative activities; and (3) audit and review Medicaid claims to ensure that Medicaid payments are appropriately made.

Further, we found that in many instances State Medicaid agencies do not currently review the CPE submitted by another unit of government to confirm that the CPE properly reflects the actual expenditure by the unit of government for providing Medicaid services or performing administrative activities. These circumstances do not serve to advance or promote the fiscal integrity of the Medicaid program. By establishing minimum standards for the documentation supporting CPEs, we anticipate that the provisions of this regulation would serve to enhance the fiscal integrity of CPE practices within the Medicaid program.

The provision of the regulation regarding certified public expenditures is also a clarification to existing Federal statutory instruction at 1903(w)(6)(A). Consistent with this explicit statutory instruction, a certified public expenditure means that State or local tax dollars were used to satisfy the cost of serving Medicaid individuals (and the cost of providing inpatient and outpatient hospital services to the uninsured for purposes of Medicaid DSH payments). It is not clear what method other than identification of the cost of providing services to Medicaid individuals (and certain uninsured costs for purposes of Medicaid DSH payments) would be appropriate to make Federal matching funds available for purposes of health care providers certifying public expenditures.

The cost documentation process is necessary to demonstrate the services that have been provided to Medicaid individuals. The burden associated with cost reporting for hospitals and nursing facilities should be minimal because nationally recognized cost reports are already utilized by these health care providers. For non-hospital and non-nursing facility services in Medicaid, we note that a nationally recognized, standard cost report does not exist. Because of this, we are publishing a standardized cost reporting form that can be used to document the costs of providing non-institutional services to Medicaid individuals. The purpose of this standardized form is to minimize the burden associated with the review of expenditures for non-institutional services provided to Medicaid individuals.

CMS has developed a general Medicaid Cost Reporting Protocol available on the CMS Web site at *http://www.cms.hhs.gov/MedicaidGenInfo/Downloads/Cost Limits Regulation CMS–2258-FC.zip* that specifically addresses methods under which institutional and non-institutional Medicaid costs will be determined for purposes of CPEs.

80C. Comment: One commenter asked if the State's obligation to demonstrate that a certifying entity is a unit of government, is a one-time obligation, or must the State so certify to support each and every CPE.

80R. Response: Section 433.51(b)(2) requires that ''certified public expenditures must be * * * supported by auditable documentation * * * that explains whether the contributing unit of government is within the scope of the exception to limitations on provider-related taxes and donations.'' Therefore, the unit of government must attest to its governmental status and produce the necessary cost documentation for each CPE submitted to the Medicaid Agency, on which Federal matching funds would be claimed. States will have governmentally-operated health care provider determinations on file to verify the governmental status of the certifying health care provider.

A governmental entity that is not a health care provider which pays for a covered Medicaid service furnished by a health care provider (whether governmentally-operated or not) can certify its actual expenditure, in an amount equal to the Medicaid State plan rate (or the approved provisions of a waiver or demonstration, if applicable) for the service. In this case, the CPE would represent the expenditure by the governmental unit to the service provider (and would not necessarily be related to the actual cost to the health care provider for providing the service) on behalf of the State Medicaid agency. The governmental entity that is not a health care provider must submit a certification statement to the State Medicaid agency attesting that the total computable amount of its claimed expenditures are eligible for FFP, in accordance with the Medicaid State plan and the revised provisions of § 433.51. That certification must be submitted and used as the basis for a State claim for FFP within 2 years from the date of the expenditure.

81C. Comment: One commenter expressed concern about a statement in the preamble that ''certification must be submitted and used as the basis for a State claim for FFP within two years from the date of expenditure,'' claiming that the Medicaid statute does not presently impose such a two-year limit.

81R. Response: A CPE means that State or local tax dollars were used to satisfy the costs of providing services to Medicaid individuals. Federal matching funds are available as a percentage of such costs, incurred or rates paid under the authority of the Medicaid State plan, in recognition that a unit of government has satisfied the Medicaid payment in full (that is, both State and Federal share) for services provided to Medicaid individuals.

The statement within the preamble of the regulation was included to ensure compliance with section 1132(a)(2) of the Act and 45 CFR 95.7 which require that any claim by a State for payment with respect to an expenditure made be filed within the 2 year period.

CMS has developed a general Medicaid Cost Reporting Protocol available on the CMS website that specifically addresses methods under which institutional and non-institutional Medicaid costs will be determined for purposes of CPEs.

82C. Comment: A number of commenters stated that the administrative burden would be placed on the State if it is required to periodically audit and review certified public expenditures as stipulated in the proposed regulation.

82R. Response: The provision of the regulation regarding certified public expenditures clarifies and implements the statutory instruction at 1903(w)(6)(A). Consistent with this explicit statutory instruction, a certified public expenditure means that State or local tax dollars were used to satisfy the cost of serving Medicaid individuals (and the cost of providing inpatient and outpatient hospital services to the

uninsured for purposes of Medicaid DSH payments). CMS believes States would support the establishment of periodic audit and review to ensure the fiscal integrity of CPE practices within their Medicaid programs.

For hospital and nursing facility services, nationally recognized cost reports are already available and are already audited by the Medicare fiscal intermediary. Therefore, the State's burden to review these cost reports should be minimal. For non-hospital and non-nursing facility services in Medicaid, we note that a nationally recognized, standard cost report does not exist. Because of this, we are publishing a standardized cost reporting form that can be used to document the costs of providing non-institutional services to Medicaid individuals. The purpose of this standardized form is to minimize the burden associated with the review of expenditures for non-institutional services.

CMS has developed a general Medicaid Cost Reporting Protocol available on the CMS website that specifically addresses the methods under which institutional and non-institutional costs will be determined for purposes of CPEs.

83C. Comment: One commenter noted the new mandates required of States and local governments with respect to CPEs and expressed the opinion that the Federal government should fund 100 percent of all costs associated with these mandates.

83R. Response: Each State is responsible for the proper and efficient administration of its Medicaid program. Expenses incurred for administration of the Medicaid program are eligible for Federal matching funds at the regular 50 percent administrative matching rate.

84C. Comment: Numerous commenters recommended that CMS permit the use of CPEs for health care providers regardless of the payment methodology provided under the State plan. These commenters indicated that health care providers will incur costs associated with providing care to Medicaid individuals whether they are paid on a cost basis or not. An example was provided. If a health care provider incurs $100 in cost in providing care to a Medicaid individual, but the payment methodology is a prospective one that results in a $90 payment, the health care provider could still certify that it incurred $100 in costs in connection with care for that individual. Because the payment is limited to $90, however, only $90 of the certification would be eligible for federal match. These commenters also argue that when payment is not based on a cost methodology, CMS should allow health care providers to certify costs associated with care to Medicaid individuals not to exceed the amount of payments provided under the State plan methodology. Other commenters stipulated that once CMS has approved a payment methodology in the State's plan, demonstration of the expenditure, other than the usual claim for the Medicaid service provided, should not be necessary.

84R. Response: Medicaid State plan rate methodologies are incompatible with a governmentally-operated health care provider's use of certified public expenditures. The Medicaid State plan is the vehicle for determining expenditures that are eligible for Federal matching funds. Section 433.51 states that the CPE must, itself, be eligible for FFP. If the State plan does not contain an actual cost reimbursement methodology, then the governmentally-operated health care provider may not use a CPE because it would not be able to establish an expenditure under the Medicaid State plan, consistent with the requirements of 45 CFR 95.13, where there was no cost incurred that would be recognized under the Medicaid State plan. A health care provider cannot establish an expenditure under the Medicaid State plan by asserting that it would pay itself the Medicaid State plan rate. A cost reimbursement methodology specified within the Medicaid State plan would allow for reimbursement as a percentage of the governmentally-operated health care provider's cost of services to Medicaid individuals.

85C. Comment: One commenter is particularly concerned that the proposed regulation would require proof of actual Medicaid expenditures in order to CPE. The commenter stipulated that the Medicaid statute does not specifically limit the use of certifications of expenditures to Medicaid costs, but to expenditures under the Medicaid statute, which also include DSH payments. Therefore, CPEs could only be used to fund Medicaid expenditures that are stated on a cost report and would prevent governmental providers from using CPEs for DSH as well as for other costs of caring for Medicaid individuals not reflected in cost reporting methodologies.

85R. Response: The provisions of the regulation do not prohibit a State from utilizing CPEs for purposes of DSH payments, nor for non-institutional services provided to Medicaid individuals. Only certain hospitals within a State are eligible to receive DSH payments. DSH payments are limited to each qualifying hospital's uncompensated care costs associated with providing inpatient and outpatient hospital services to Medicaid individuals and to individuals with no source of third party coverage for the inpatient and outpatient hospital services they received. These costs would be derived from the Medicare 2552–96 hospital cost report, a nationally recognized cost report which all hospitals utilize. To determine the costs eligible for purposes of CPE, States and governmentally-operated hospitals would utilize audited hospital financial statements and information from the Medicaid Management Information System (MMIS) to properly allocate the eligible Medicaid and uninsured costs from the hospital cost report.

CMS has developed a general Medicaid Cost Reporting Protocol available on the CMS website that specifically addresses the methods under which institutional and non-institutional costs will be determined for purposes of CPEs.

86C. Comment: One commenter recommended that CMS modify the proposed regulation to allow a payment and corresponding CPE based on a current, inflated cost report without any reconciliation process and that any changes to costs will be captured in future cost reports.

86R. Response: The CPE process inherently requires a reconciliation of the certifying unit of government's actual costs of providing services to Medicaid individuals. Under a Medicaid cost reimbursement payment system funded by CPEs, States may utilize most recently filed cost reports to develop interim Medicaid payment rates and may trend these interim rates by an applicable health care-related index. Interim reconciliations must be performed by reconciling the interim Medicaid payment rates to the filed cost report for the spending year in which interim payment rates were made. Final reconciliation must also be performed by reconciling the interim payments and interim adjustments to the finalized cost report for the spending year in which interim payment rates were made.

87C. Comment: One commenter noted that they currently offset Medicaid expenditures using CPEs through the UPL financing to outpatient hospitals, nursing facilities and home health agencies. The commenter specifically requested that this offset continue to be allowed, but only when applied to Medicaid expenditures.

87R. Response: It is not clear what ''offsetting Medicaid expenditures using CPEs through UPL financing'' means. A CPE means that State or local tax dollars were used to satisfy the cost of serving Medicaid individuals. Historically,

Medicaid upper payment limits (UPLs) for governmentally health care providers were not limited to the cost of providing services to Medicaid individuals and often ''UPL payments'' were made in excess of Medicaid costs. However, UPL payments that were made in excess of Medicaid costs could not be funded through CPEs based on the statutory definition, which limits the CPE funding source to allowable Medicaid (and DSH) cost.

Under the provisions of this regulation, the UPL for governmentally-operated health care providers is Medicaid cost. Any revenues received by a governmentally-operated health care provider under the authority of the Medicaid State plan must be offset prior to determining if any uncompensated Medicaid costs exist that would be eligible under the CPE funding source.

88C. Comment: One commenter asked what the CPE requirements are when a unit of government makes a payment to a health care provider not operated by a unit of government.

88R. Response: A governmental entity that is not a health care provider which pays for a covered Medicaid service furnished by a health care provider (whether governmentally-operated or not) can certify its actual expenditure, in an amount equal to the Medicaid State plan rate (or the approved provisions of a waiver or demonstration, if applicable) for the service. In this case, the CPE would represent the expenditure by the governmental unit to the service provider (and would not necessarily be related to the actual cost to the health care provider for providing the service). The governmental entity that is not a health care provider must submit a certification statement to the State Medicaid agency attesting that the total computable amount of its claimed expenditures are eligible for FFP, in accordance with the Medicaid State plan and the revised provisions of § 433.51. That certification must be submitted and used as the basis for a State claim for FFP within 2 years of the expenditure consistent with filing requirements at section 1132(a)(2) of the Act and 45 CFR 95.7.

89C. Comment: A few commenters asked whether it would it be possible for a unit of government that pays a private university for physician services to certify those funds under Medicaid, if the services provided by those physicians are approved under the State plan amendment, and would it be possible for State universities to certify as an expenditure the portion of a faculty physicians' salary spent treating Medicaid individuals.

89R. Response: The first part of the question relates to a unit of government making payments to a private health care provider. A governmental entity that is not a health care provider which pays for a covered Medicaid service furnished by a health care provider (whether governmental or not) can certify its actual expenditure, in an amount equal to the Medicaid State plan rate (or the approved provisions of a waiver or demonstration, if applicable) for the service. In this case, the CPE would represent the expenditure by the governmental unit to the service provider (and would not necessarily be related to the actual cost to the health care provider for providing the service).

The second part of the question raises the possibility of a State university certifying the expenditures for the portion of a faculty physician's salary associated with the delivery of clinical services to Medicaid individuals. CMS notes that the relationships between a faculty physician's clinical practice and the State university vary on a case by case basis. For example, some State universities require faculty physicians to provide clinical services in private faculty practice groups, while other State universities consider faculty physicians employees of the university when providing clinical care. In light of these arrangements, the response to the second part of this question can only be answered based on whether or not the State university is considered a unit of government (State university teaching hospitals are recognized as units of government in the statute and regulation) and whether or not the faculty physician is actually considered an integral part of that unit of government when delivering clinical care. If the State university is a unit of government and is the health care provider of the physician services, then the State university teaching hospital may generate a CPE from its own costs if the Medicaid State plan (or the approved provisions of a waiver or demonstration, if applicable) contains an actual cost reimbursement methodology. If this is the case, the State university may certify the costs that it actually incurred that would be paid under the Medicaid State plan. If the State plan does not contain an actual cost reimbursement methodology, then the State university may not use a CPE because it would not be able to establish an expenditure under the plan, consistent with the requirements of 45 CFR 95.13.

90C. Comment: One commenter noted that the preamble to the regulation indicated that a claimable expenditure must involve a shift of funds (either by an actual transfer or a debit in the accounting records of the contributing unit of government and a credit in the records of a provider of medical services) and cannot merely be a refund or reduction in accounts receivable. The commenter stated that this restriction is unclear and appears unnecessary. The commenter described that government health care providers are directly funded by legislative appropriations and/or recurring revenues, then these health care providers certify allowable Medicaid expenditures through the submission of claims for covered services. The commenter went on to state that these claims are valued at the Medicaid reimbursement rate in the approved State plan and support the State's claim for FFP. Therefore, the commenter argued, there is no need for further accounting transactions by the health care provider or governmental entity.

90R. Response: According to 45 CFR 95.13(b), for expenditures for services under the Medicaid program, an expenditure is made ''in the quarter in which any State agency made a payment to the service provider.'' There is an alternate rule for administration or training expenditures at 45 CFR 95.13(d), under which the expenditure is made in the quarter to which the costs were allocated or, for non-cash expenditures, in the quarter in which ''the expenditure was recorded in the accounting records of any State agency in accordance with generally accepted accounting principles.'' The State Medicaid Manual, at section 2560.4.G.1.a(1), indicates that ''the expenditure is made when it is paid or recorded, whichever is earlier, by any State agency.'' These authorities clearly indicate that there must be a record of an actual expenditure, either through cash or a transfer of funds in accounting records, in order for the expenditure to be considered eligible for Federal Financial Participation (FFP).

Moreover, as defined at 45 CFR 95.13(b), a Medicaid expenditure occurs when any State agency makes a payment to the service provider. Pursuant to § 433.10(a), the expenditure must be a total computable payment, including both Federal and State share, which forms the basis of the claim to draw down the corresponding FFP in accordance with the Federal Medical Assistance Percentage (FMAP) rate. These provisions clearly demonstrate that a unit of government cannot merely submit claims that would be considered somehow equivalent to certified public expenditures in order for the State to receive Federal matching funds.

The options available to a unit of government for purposes of compliance with the CPE provisions of the regulation depend on whether or not the unit of government is the provider of the service. A governmental entity that is not a health care provider and that pays for a covered Medicaid service furnished by a health care provider (whether governmentally-operated or not) can certify its actual expenditure in an amount equal to the Medicaid State plan rate (or the approved provisions of a waiver or demonstration, if applicable) for the service. In this case, the CPE would represent the expenditure by the governmental unit to the service provider on behalf of the State Medicaid agency (and would not necessarily be related to the actual cost to the health care provider for providing the service).

If the unit of government is the health care provider, then it may generate a CPE from its own costs if the Medicaid State plan (or the approved provisions of a waiver or demonstration, if applicable) contains a cost reimbursement methodology. If this is the case, the governmentally-operated health care provider may certify the costs that it actually incurred that would be reimbursed under the Medicaid State plan. If the Medicaid State plan does not contain an actual cost reimbursement methodology, then the governmentally-operated health care provider may not use a CPE because it would not be able to establish an expenditure under the authority of the Medicaid State plan. This is consistent with the requirements of 45 CFR 95.13, where there was no cost incurred that would be recognized under the Medicaid State plan. A governmentally-operated health care provider cannot establish an expenditure under the Medicaid State plan by asserting that it would pay itself the Medicaid State plan rate.

91C. Comment: A few commenters disagreed that a CPE equals 100 percent of a total computable Medicaid expenditure. The commenter stated that a certifying governmental unit may fund all or part of the cost within the health care provider. For example, the commenter noted that a governmental health care provider or entity may be responsible for funding the cost of prospective rate increases while the State Medicaid agency continues payments at the base period rate.

91R. Response: Statutory and regulatory provisions require that an expenditure must be a total computable payment, including both Federal and State share, in order to form the basis of a State's claim to draw down the corresponding FFP in accordance with the Federal Medical Assistance Percentage (FMAP) rate. It is possible that a State uses two different funding sources for two different payments under different reimbursement methodologies in the Medicaid State Plan. For instance, the State Medicaid agency may use general fund appropriations to finance the non-Federal share of base Medicaid payments to a governmentally-operated health care provider. Under a separate reimbursement methodology in the approved Medicaid State Plan, the governmentally-operated health care provider may be eligible to receive reimbursement for its Medicaid costs in excess of base Medicaid payments received. Under the latter reimbursement methodology, the governmentally-operated health care provider could certify the uncompensated portion of its Medicaid costs (that is, total Medicaid costs minus total Medicaid revenues) and Federal financial participation would be available as a percentage of its total computable costs less revenues received as a CPE eligible for additional FFP.

The options available to a unit of government for purposes of compliance with the CPE provisions of the regulation depend on whether or not the unit of government is the provider of the service. A governmental entity that is not a health care provider and that pays for a covered Medicaid service furnished by a health care provider (whether governmentally-operated or not) can certify its actual expenditure in an amount equal to the Medicaid State plan rate (or the approved provisions of a waiver or demonstration, if applicable) for the service. In this case, the CPE would represent the expenditure by the governmental unit to the service provider on behalf of the State Medicaid agency (and would not necessarily be related to the actual cost to the health care provider for providing the service).

If the unit of government is the health care provider, then it may generate a CPE from its own costs if the Medicaid State plan (or the approved provisions of a waiver or demonstration, if applicable) contains a cost reimbursement methodology. If this is the case, the governmentally-operated health care provider may certify the costs that it actually incurred that would be reimbursed under the Medicaid State plan. If the Medicaid State plan does not contain an actual cost reimbursement methodology, then the governmentally-operated health care provider may not use a CPE because it would not be able to establish an expenditure under the authority of the Medicaid State plan. This is consistent with the requirements of 45 CFR 95.13, where there was no cost incurred that would be recognized under the Medicaid State plan. A governmentally-operated health care provider cannot establish an expenditure under the Medicaid State plan by asserting that it would pay itself the Medicaid State plan rate.

92C. Comment: One commenter argued that the requirement of a CPE in the school setting is unnecessary because the majority of Medicaid costs in schools are funded ''up front'' using local tax dollars to cover the cost of services on a per child basis. Therefore, school districts are not making money on Medicaid reimbursements relative to the outlay of actual costs.

92R. Response: The provision of the regulation regarding certified public expenditures is a clarification to existing Federal statutory instruction at 1903(w)(6)(A). Consistent with this explicit statutory instruction, a certified public expenditure means that State or local tax dollars were used to satisfy the cost of serving Medicaid individuals (and the cost of providing inpatient and outpatient hospital services to the uninsured for purposes of Medicaid DSH payments). The cost documentation process is necessary to demonstrate that services have been provided to Medicaid individuals. Federal financial participation is available as a percentage of the total allowable costs. It is not clear what method other than identification of the cost of providing services to Medicaid individuals would be appropriate to make Federal matching funds available for purposes of health care providers certifying public expenditures.

D. Cost Limit for Providers Operated by Units of Government (§ 447.206)

93C. Comment: Numerous commenters argued strongly that CMS lacks the statutory authority to impose a provider specific cost limit. The commenters did not believe that CMS has the authority to change the existing upper payment limit (UPL) regulations in order to implement this new limit. These commenters believe that the NPRM represents a significant and unjustified departure from CMS' earlier understandings and implementation of Congressional intent and in some cases direct Congressional direction. Further, the commenters stated that Congress itself has rejected cost-based reimbursement principles and has historically through passage of various amendments to the Social Security Act (including the Boren Amendment in 1980 and its repeal in 1997) endorsed State flexibility in establishing

reimbursement rates for Medicaid providers.

Several commenters noted that the current Administration has repeatedly asked Congress to impose a cost limit on payments to public health care providers and Congress has refused to legislate this action. The commenters believe that because the Administration's request and the Congress' refusal to legislate only highlight the lack of authority for the proposed cost limit. Other commenters specified that State Medicaid programs feature a variety of targeted supplemental payments that enable States to tailor their Medicaid programs to meet the unique needs of their population. Eliminating the aggregate nature of the UPL restricts States' flexibility to address local needs through reimbursement policies and runs counter to the Administration's commitment and Congress' efforts to enhance State flexibility in managing their Medicaid program. Other commenters mentioned that the proposed cost limit is contrary to section 1902(a)(13) of the Act, which has always been interpreted to support rate setting flexibility on the part of States. One commenter questioned why CMS wants to limit States' flexibility in distributing supplemental payments.

93R. Response: We disagree with this comment. Under section 1902(a)(30)(A) of the Act, the Secretary has broad authority to set upper payment limits to ensure that Medicaid payments are ''consistent with efficiency, effectiveness and quality of care.'' While section 1902(a)(13) of the Act no longer contains any general requirements that States pay for Medicaid institutional services on a cost, or cost-related basis, the Secretary retains the authority and responsibility to ensure that Medicaid payments are reasonable. Under the principles of Office of Management and Budget Circular A–87, governmental grantees and subgrantees are generally limited to reasonable costs and, as that term is defined, there is no provision for profit or other amounts above cost. A provider-specific cost limit is consistent with those principles.

Moreover, a provider-specific cost limit does not restrict State flexibility to use flexible rate systems for governmentally-operated health care providers that might, for example, encourage certain types of care or include performance incentives. All such a limit does is ensure that any such flexible rate system not result in payment in excess of actual documented costs. Such a limit is not designed to restrict the ability of the State to address local needs, since States may provide for payment of the full cost of Medicaid services.

94C. Comment: Another commenter stated that States are in a better position to decide how best to use their Medicaid resources and this proposed regulation would increase Federal control over how States spend their Medicaid funds. Most commenters recommended that the proposed cost limit be eliminated for all types of health care providers and the current Medicare UPL for government providers be maintained. Other commenters pointed out that if a State employs a prospective payment system the prospective rate is an estimate and it will not correspond precisely to the actual costs incurred. (S.D. Dept. of Soc. Servs., DAB No. 934 (1988)). According to the commenter, the DAB held that these rates were not subject to later adjustment based on actual costs and there was no unfound profit when payments exceeded costs. The commenters noted in other decisions the DAB has distinguished the costs incurred by providers from the rates charged by providers to the State, and it has held that the latter are what form the basis of the State's claims for expenditures.

Several other commenters cited specific Departmental Appeals Board (DAB) decisions that reviewed CMS' authority to hold government health care providers to a different standard than applied to private health care providers, or to limit government health care providers to actual-cost reimbursement. The commenters cited one DAB decision (Ill. Dept. of Pub. Aid, DAB No. 467 (1983)) that stated ''cost principles [do] not impose an actual cost ceiling on claims for reimbursement for medical assistance provided by state-owned [facilities],'' and that a State does not impermissibly profit where its claim for FFP is based on the cost it incurs in reimbursing facilities according to a prospective class rate.

94R. Response: The cited DAB decisions were issued in the absence of rulemaking under the authority of section 1902(a)(30)(A) to ensure that provider rates are consistent with efficiency, economy and quality of care. This final rule establishes CMS authority to implement an provider-specific upper payment limit based on documented costs of furnishing covered Medicaid services to eligible individuals. A provider-specific cost limit does not restrict State flexibility to use flexible rate systems for governmentally-operated health care providers that might, for example, encourage certain types of care or include performance incentives. All such a limit does is require that any such flexible rate system not result in payment in excess of actual documented costs. In this context, we anticipate that the provider-specific payment limits would only affect health care providers who are diverting Medicaid funds for other purposes, since that is the only circumstance in which Medicaid payments would not align with Medicaid costs. This circumstance necessarily results in a diminution of the resources available for care to Medicaid individuals.

By requiring that Medicaid payments align with Medicaid costs, we are ensuring that governmentally-operated providers use resources available through Medicaid payment rates to serve the Medicaid individuals. In other words, because anticipated Medicaid payments are an element in setting budgets, we anticipate that limiting matchable Medicaid revenues to Medicaid costs will result in the expansion of resources available to serve Medicaid individuals. With respect to the comment regarding the use of prospective rate systems, several OIG audits have found that such prospective systems have not resulted in accurate determinations of uncompensated care costs related to the disproportionate share hospital hospital-specific limits. Thus, we have elected not to provide any special rule for prospective payment systems in the new upper payment provisions.

The cited Departmental Appeals Board cases were decided under a different regulatory framework and do not limit our authority to issue new regulations to address the issue of governmentally-operated health care providers. Moreover, as States have evolved specialized payment systems to address the needs of governmentally-operated health care providers, it has become necessary to ensure the reasonableness of such payment systems using a specialized upper payment limit measure.

95C. Comment: Numerous comments disagreed with the change to the existing UPL regulations. The commenters argued that the new provider-specific limit for governmentally-operated providers will potentially create a system where Medicaid payments for private facilities could be higher than payments to governmentally-operated health care providers for the same services. These commenters urged CMS to reconsider these changes and that if health care providers must be held to an individual UPL test, the standard for determining the UPL for both private and government operated health care

providers be at least the same standard that exists currently. Other commenters recommended that the current aggregate UPLs based on Medicare payment principles for all categories of health care providers be maintained. Another commenter recommended that CMS could achieve its goals by revising the institutional and acute care Medicaid UPL calculations to no more than allowable Medicare cost for each of the three classes cited in § 447.272.

95R. Response: The provider-specific cost-based upper payment limit for governmentally-operated health care providers does not necessarily mean that governmentally-operated health care providers will receive lower rates than private health care providers. Governmentally-operated health care providers not receiving Medicaid payments in excess of costs, would not be adversely impacted by the Medicaid cost limit and would actually be eligible to receive greater Medicaid revenues, up to the cost limit. Non-governmentally-operated health care providers are not affected by the cost limit provision of the regulation and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements. While the provisions of the regulation do not impose a Medicaid cost limit on private health care providers, we have found during recent reviews of Medicaid reimbursement methodologies, States typically reimburse private health care providers at rates less than the cost of serving Medicaid eligible individuals.

In other words, governmentally-operated health care providers that need additional Medicaid funds to serve their Medicaid individuals will continue to have access to those funds. By requiring that Medicaid payments align with Medicaid costs, we are ensuring that governmentally-operated health providers use resources available through Medicaid payment rates to serve Medicaid individuals. It is true that the provider-specific payment limits would prevent health care providers from diverting Medicaid funds for other purposes since, in that circumstance, Medicaid payments would not align with Medicaid costs. Thus, the provider-specific limits protect Medicaid individuals by ensuring that Medicaid resources are available for their care. We anticipate that, because Medicaid revenues are an element in setting budgets, the provider-specific limit will actually result in the expansion of resources available to serve Medicaid individuals.

96C. Comment: Other commenters pointed out that in the past CMS has expressly recognized the potential financial implications of limiting reimbursement to an individual health care provider's cost and the importance of the aggregate UPL system for preserving access to Medicaid services, particularly with regard to safety-net providers. In fact, commenters noted that CMS, in response to comments within the 2002 final UPL rule, reasoned that a State could increase payments for particular hospitals and decrease payment levels at other county and local hospitals where the low-income patient load was less heavy to ensure that funding to more intensively utilized public hospitals was not jeopardized.

96R. Response: We do not believe that the new upper payment limit will jeopardize access to Medicaid services. Indeed, the new limit will ensure that Medicaid revenues are used to support Medicaid services and are not diverted for other purposes. Consistent with the new upper payment limit, States could increase payments for particular hospitals and decrease payment levels at other county and local hospitals where the low-income patient load was less heavy to ensure that funding to more intensively utilized public hospitals was not jeopardized. Medicaid payments can continue to effectively reimburse governmentally-operated health care providers that serve high low-income patient loads, both through payment of the full cost of Medicaid services, and through disproportionate share hospital payments for uncompensated care costs. Non-governmentally-operated health care providers are not affected by the cost limit provision of the regulation and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements. While the provisions of the regulation do not impose a Medicaid cost limit on private health care providers, we have found during recent reviews of Medicaid reimbursement methodologies, States typically reimburse private health care providers at rates less than the cost of serving Medicaid eligible individuals.

97C. Comment: Several commenters commented that CMS has failed to explain why it is changing its position regarding the flexibility afforded to states under the current UPL program. These commenters asserted that CMS, through court documents and its 2002 UPL final rule reinforced this concept of State flexibility. They believe that is disregarding without explanation its prior approach to give States flexibility under the UPL system to address the special needs, including the financial distress, of health care providers through supplemental payments. The commenters also stated that while CMS says that it has examined State Medicaid financing arrangements and found that ''many'' States are making supplemental payments to government-operated health care providers in excess of cost and that this excess payment is then used to subsidize health care operations unrelated to Medicaid, or is returned to the State as a source of revenue, CMS provides no data or factual support. Commenters noted that the proposed regulation lacked information on how many States are making such ''excess payments'' or any specific information regarding how health care providers are using these excess payments.

97R. Response: The preamble to the proposed regulation contained a detailed description of the concerns that led to this issuance. Specifically, we found that many States make supplemental payments to governmentally-operated health care providers that are in excess of cost. These health care providers, in turn, use that excess of Medicaid revenue over cost to subsidize health care (or other) operations that are unrelated to Medicaid, or they may return a portion of the supplemental payments in excess of cost to the States as a source of revenue. These practices effectively divert Medicaid funds to non-Medicaid purposes, or overstate the total computable expenditure that is being made. We do not think it is necessary to identify specific States which may have proposed or may have implemented such arrangements described in this regulation. We have worked with those States to eliminate such arrangements whenever we discover them. This process can be politically delicate. Listing States and questionable arrangements would not serve the public interest. The States themselves sought to protect their financing methodologies from scrutiny and kept these matters from the public eye. Since 2003, we have worked successfully with 30 States in a consistent manner to terminate certain payment arrangements that did not meet statutory requirements and worked with States to develop alternative methods of financing.

98C. Comment: A few commenters asserted that the current practice of following Medicare payment principles would not result in excessive payments to providers. Their first point is that CMS is the agency that sets Medicare payment rates. Second, the commenters pointed to CMS' 2002 final rule

implementing UPL requirements and the position that at the time Medicare payment principles resulted in reasonable payment rates and that States should retain flexibility to make enhanced payments to selected public hospitals under the aggregate limit. They noted that CMS indicated in the 2002 final rule that the UPL as implemented would assure that payments were consistent with efficiency, economy and quality of care. The commenters stated that CMS has offered no logical basis for changing these determinations or offered any explanation as to why Medicare payments are not reasonable for government health care providers.

98R. Response: Medicare rates do not distinguish between governmentally-operated and non-governmentally-operated health care providers. Furthermore, because Medicare is not a federal-state program, but is federal-only, the incentive structure for governmentally-operated health care providers is different. The Medicaid program is jointly funded by Federal, State, and local governments. We do not find it appropriate that units of State or local government would ''profit'' from Federal taxpayer dollars that are intended to match a percentage of the cost of providing services to Medicaid individuals.

The new upper payment limit for governmentally-operated health care providers will more accurately ensure efficient and effective payment levels for the full cost of Medicaid services, and will ensure that higher Medicaid payments result in improved quality of care for Medicaid individuals. Governmentally-operated health care providers would be able to receive full payment for Medicaid costs, and those with particularly high costs to provide Medicaid services would be able to receive Medicaid payments to support those costs. The provider-specific payment limits would limit health care providers from diverting excess Medicaid funds for other purposes since, in that circumstance, Medicaid payments would not align with Medicaid costs. In doing so, the provider-specific limits protect Medicaid individuals by ensuring that Medicaid resources are available for their care. We anticipate that, because Medicaid revenues are an element in setting budgets, the provider-specific limit will actually result in the expansion of resources available to serve Medicaid individuals.

99C. Comment: Several commenters stated that the provisions of the regulation violates section 705(a) of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA). The commenters specify that through BIPA, Congress provided CMS explicit instruction to adopt an aggregate Medicare-related upper payment limit (UPL). The commenters argued that the proposed cost limit deviates significantly from Congress' clear mandate that UPLs: (1) Be aggregate limits and (2) include a category of facilities that are ''not State-owned or operated.'' Congress explicitly endorsed the establishment of a UPL based on Medicare payment principles, not costs.

99R. Response: The conditions set forth in section 705(a) of BIPA, to publish a final regulation based on the proposed regulation announced on October 5, 2000, were met by the publication of a final regulation on January 12, 2001, at 66 FR 3148. Section 705 of BIPA did not purport to remove the Secretary's authority to revise such regulation as necessary to interpret and implement the underlying statutory authority. However payments specifically permitted by section 705 of BIPA are not subject to the upper payment limits provision of the regulation.

100C. Comment: Numerous commenters disagreed with CMS' assertion that Medicaid payment in excess of cost to governmentally-operated health care providers is not consistent with the statutory principles of economy and efficiency as required by section 1902(a)(30)(A) of the Act. They asserted that if CMS' goal is to assure that Medicaid payments are consistent with economy and efficiency there is no basis for imposing a cost-based reimbursement system for government-operated health care providers. Other commenters stated that the provisions of the regulation will directly harm the ability of States to meet their statutory obligation to ensure access to care for Medicaid individuals. By prohibiting States from reimbursing a health care provider for more than costs, and restricting States from making enhanced payment to health care providers in financial need, CMS is imposing a funding restriction that will be passed on from the States to government health care providers. States, not CMS, as a result will be faced with the concerns from beneficiary advocates when access to care is compromised.

100R. Response: We disagree with the premise that it could be consistent with efficiency and economy and quality of care to provide for payment to government providers in excess of cost for Medicaid services. Under the Medicaid program, the federal government shares with State and local governments in expenditures for medical assistance; it is not consistent with that relationship for the federal government to share in amounts in excess of the actual cost of medical assistance to State and local governments. Payment above the actual cost of medical assistance effectively diverts funding from the purposes authorized by the federal statute to be used for other, unauthorized purposes.

We also disagree with the premise that the new upper payment limit will jeopardize access to Medicaid services. Payment to government providers may cover the full cost of Medicaid services. Indeed, the new limit will ensure that Medicaid revenues are used to support Medicaid services and are not diverted for other purposes.

Under the new upper payment limit, States may continue to make increased Medicaid payments for particular governmentally-operated health care providers that have higher cost structures because of high low-income patient loads and decreased payment levels for other governmentally-operated health care providers with lower cost structures because they serve fewer low-income patient loads. These payments may provide full payment for the costs of serving Medicaid individuals. Governmentally-operated health care providers not receiving Medicaid payments in excess of costs would not be adversely impacted by the cost limit and would actually be eligible to receive greater Medicaid revenues up to the cost limit.

We recognize that some States have made excessive payments in an attempt to address burdens providers may face in furnishing non-Medicaid uncompensated care. While that goal is laudable, Medicaid funding is limited to authorized purposes. In general, those purposes are limited under section 1905(a) of the Act to covering costs of covered services for eligible individuals. The Medicaid statute expressly permits States to make disproportionate share hospital payments up to specified limits, which can address certain non-Medicaid costs. If Congress had wished to provide other mechanisms to address non-Medicaid costs, it could have done so.

Non-governmentally-operated health care providers, including many of the ''public'' safety net health care providers, are not affected by the cost limit provision of the regulation and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements.

101C. Comment: One commenter stated that creating a new payment system through the rule making process instead of the legislative process does not allow for provider or public assistance. The commenter further stated that the ability to only provide comment on the rule by its nature sets up antagonistic positions instead of collaborative and creative programs.

101R. Response: The provisions of this regulation do not create a new payment system for governmentally-operated health care providers. States still have flexibility to determine the appropriate payment system. This regulation is part of the Secretary's Federal oversight responsibility to ensure that Medicaid payments are consistent with statutory requirements. The Secretary is exercising that authority through the rule making process, as required under the Administrative Procedure Act. We do not believe that process is antagonistic and we regret that the commenter sees it as such. We value the comments received and have considered them carefully. Moreover, the development of this regulation has been strongly influenced by ongoing Medicaid State plan processes, in which States have the opportunity to explain and justify their practices. In those processes, CMS tries to work collaboratively with States to develop the framework for State Medicaid programs that should embody the statutory goals of the Medicaid program. This regulation addresses payment practices that do not appear to embody the statutory goals of the program but are, instead, designed to divert Medicaid funding for use for other purposes, and that do not directly benefit Medicaid eligible individuals.

102C. Comment: A few commenters questioned how the proposed cost limit interrelates with existing UPL transition provisions. Some commenters were confused since the UPLs as modified by the proposed regulation would be individual limits, as opposed to aggregate, yet the UPL transition amounts to be phased out are still an aggregate amount. They questioned whether the excess amount to be phased out supposed to be now an individual provider-specific amount. The commenters were particularly concerned since proposed § 447.206 provides for no exception to reflect transition payments. Other commenters specifically requested that the proposed regulation incorporate these statutorily-mandated transition provisions, similar to how they are handled in the current regulations at §§ 447.272 and 447.321. Another commenter expressed dissatisfaction that those States that are still out of compliance with the last round of changes to the UPL rules due to the transition period they received will also not have to conform to the new cost limit provisions by the September 1, 2007 effective date. The commenter was upset that those that had previous occurrences of Medicaid financing abuses will be allowed to continue transitioning out of their abusive systems, while States who have not abused Medicaid financing will have to come into immediate compliance. The commenter implored CMS to develop a fair implementation process and standardized implementation date that does not continue to reward those that are not currently in compliance.

102R. Response: The provisions of the regulation did not make any changes to existing UPL transition periods in the regulations at §§ 447.272 and 447.321, which means that any remaining UPL transition payments can continue to be made through the end of previously established transition periods. Only States that qualified for 8-year transition periods continue to make UPL transition payments. These UPL transition periods are experiencing a significant phase-down (that is, affected States have phased down to 10 percent of the excess in 2008) and all transition periods expire at the end of Federal fiscal year 2008.

States with remaining UPL transition periods will be permitted to make their UPL transition payments to health care providers as they deem appropriate. Such UPL transition payments, payment levels of which have been previously determined, should not be factored into a specific health care provider's cost limit to demonstrate compliance with the new provisions at § 447.206. We have modified the regulation at §§ 447.272(c)(3) and 447.321(c)(3) to recognize that such transition payments, as expressly authorized by section 705 of BIPA, are not subject to the Medicaid cost limit.

103C. Comment: One commenter questioned whether the new hospital-specific test is performed separately for outpatient and inpatient hospital services or in the aggregate.

103R. Response: For purposes of compliance with the cost limit on Medicaid payments, each type of service reimbursed under the authority of the Medicaid State plan must be evaluated separately, irrespective of whether a governmentally-operated health care provider delivers more than one service eligible under the Medicaid State plan. Therefore, the inpatient and outpatient hospital-specific Medicaid cost limits must be calculated separately.

104C. Comment: One commenter requested clarification of whether the cost limit applies solely to non-state government hospitals and not to private hospitals.

104R. Response: The Medicaid cost limit provision of the regulation applies to all health care providers that are operated by a unit of government as defined in § 433.50, including hospitals. Private hospitals and other private health care providers are not subject to the cost limit provision at § 447.206.

105C. Comment: Several commenters stated that the proposed regulation is in direct conflict with advances that many States have made in recent years related to health care provider reimbursements. For example, some commenters noted that many States have developed DRG reimbursement systems consistent with the Medicare so that hospitals are reimbursed by the same methodology. Because of the proposed regulation's requirements for cost reconciliation and recoupment of any payments above cost, there is the potential that significant funds would have to be recouped annually if the DRG system is maintained. In fact, States will be forced to abandon the DRG system for government operated hospitals and return to the antiquated and inefficient cost-based system. Several other commenters stated that hospital reimbursement systems have evolved following the model of the Medicare program and its use of prospective payment systems. These reimbursement systems are intended to improve efficiency by rewarding hospitals that can keep costs below the amount paid. One commenter also noted that their PPS rates should not be equated to reasonable cost, due to the cumulative difference between medical inflation and the Medicare Economic Index.

105R. Response: The Medicaid program is jointly funded by Federal, State, and local governments. We do not find it appropriate that units of State or local government would ''profit'' from Federal taxpayer dollars that are intended to match a percentage of the cost of providing services to Medicaid individuals. Nevertheless, as we have examined Medicaid financing arrangements across the country, we have found that many States make payments to governmentally-operated providers that are in excess of cost. These health care providers, in turn, use the excess of Medicaid revenue over cost to subsidize health care operations that are unrelated to Medicaid, or they may return a portion of such payments to the State as a source of revenue. In either case, we do not find that Medicaid payments in excess of cost to

governmentally-operated health care providers are consistent with the statutory principles of economy and efficiency as required by section 1902(a)(30)(A) of the Act, nor do we find such excessive payments to be consistent with the statutory structure requiring that the Federal government match a percentage of State or local government expenditures for the provision of services to Medicaid individuals.

In addition, the proposed regulation does not require States to abandon existing DRG based payment systems or any other existing Medicaid reimbursement rate methodologies currently utilized to pay governmentally-operated health care providers. Under the Medicaid cost limit, States may continue to use existing Medicaid reimbursement rate methodologies, but will need to compare such rates to the actual cost of providing services to Medicaid individuals and make reconciling adjustments in the event of overpayments to a particular governmentally-operated health care provider. States may find such cost reconciliations to be useful inasmuch as they will permit States to better analyze the reasonableness of their Medicaid reimbursement rates.

106C. Comment: Many commenters stated that Medicare rates and the ability to calculate payments in the aggregate are reasonable because Medicare rates are reasonable and are not excessive and afford States the flexibility necessary to target resources to needy areas. One commenter questioned why CMS believed Medicare rates to be excessive. Medicare's prospective payment system recognizes that some health care providers will incur costs above Medicare rates and others will incur costs that are below payment rates and achieve a level of Medicare profit. It is the opportunity for this profit incentive that helps health care providers focus on costs and pursue efficiency. Prospective payment rates are set at a rate that in the aggregate ensure a savings to the Medicare program. States should be allowed to utilize payment rate differentials to incentivise desired provider behaviors.

106R. Response: Current upper payment limits are based on aggregate estimates of Medicare payments and are therefore calculated on a hypothetical basis, since the services at issue are not actually Medicare services. Under the current UPL, many States provide supplemental UPL payments (up to the aggregate UPL, based on the aggregate estimate of Medicare payments) to fund the non-Medicaid costs of governmentally-operated health care providers. The current limit based on a hypothetical measure is difficult to administer because the actual services at issue are Medicaid services, and yet aggregate hypothetical estimates of payments by another program create the ceiling for Medicaid payments. The Medicaid cost limit at § 447.206 is directly based on Medicaid services provided by a specific governmentally-operated health care provider; therefore, it is auditable and tangible, and it would substantially align Medicaid payments to the costs of serving Medicaid individuals.

The Medicaid program is jointly funded by Federal, State, and local governments. We do not find it appropriate that units of State or local government would ''profit'' from Federal taxpayer dollars that are intended to match a percentage of the cost of providing services to Medicaid individuals.

107C. Comment: Several commenters stated that the cost limit would prevent states from adopting payment methodologies that are economic and efficient and that promote quality and access. Therefore, the cost limit is in conflict with section 1902(a)(30)(A) of the Social Security Act. Under the proposed cost limit, States will no longer be able to meet the requirements of this statutory provision.

107R. Response: We disagree with the premise that it could be consistent with efficiency and economy and quality of care to routinely provide for payment in excess of cost for Medicaid services. The new limit will ensure that Medicaid revenues are used to support Medicaid services and are not diverted for other purposes. Under the new upper payment limit, States may continue to have increased Medicaid payments for particular governmentally-operated health care providers with high low-income patient loads and decreased payment levels at other governmentally-operated health care providers where the low-income patient load is less. These payments may provide full payment for the costs of serving Medicaid individuals. Governmentally-operated health care providers not receiving Medicaid payments in excess of costs would not be adversely impacted by the cost limit and would actually be eligible to receive greater Medicaid revenues up to the cost limit. The Medicaid cost limit provision should not force cuts to the Medicaid program, nor affect access to services. This will ensure that funding to governmentally-operated health care providers intensively used by Medicaid individuals is not jeopardized. In addition, to address the burden of non-Medicaid uncompensated care incurred by hospitals, Congress has specifically provided for States to make disproportionate share hospital payments. To the extent that more flexibility is desired, States are not precluded from developing demonstration projects to test new payment methodologies.

Non-governmentally-operated health care providers, including many of the ''public'' safety net health care providers, are not affected by the cost limit provision of the regulation and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements. It is unclear how a limit that does not apply to non-governmentally-operated health care providers would reduce services or limit access to Medicaid individuals or to the uninsured.

108C. Comment: Several commenters stated that the proposed cost limit defies simplicity of administration and ignores the best interest of Medicaid individuals as required by section 1902(a)(19) of the Act. The proposed cost limit would not enable States to meet the requirements of this statutory provision.

108R. Response: We clearly understand that the provisions of this regulation will impose an administrative burden on governmentally-operated health care providers and States to document the allowability of Medicaid claims through cost reporting. This burden is reasonable, however, because most such health care providers are already reporting costs in other contexts. The relevant cost data would have been fully or partially developed for a Medicare hospital cost report, for a Single Audit Act financial statement, or for other audited financial statements. While some adjustment may be necessary for data developed for other purposes, this is not an unreasonable burden. Moreover, this regulation would protect the best interests of Medicaid individuals because it prevents States or health care providers from diverting Medicaid funds for other purposes than Medicaid, and ensures that Medicaid resources are available for care to Medicaid individuals. We anticipate that, because Medicaid revenues are an element in setting budgets, the provider-specific limit will actually result in the expansion of resources available to serve Medicaid individuals.

109C. Comment: A few commenters specified that CMS cites the statutory restrictions on matching only Medicaid

expenditures as the basis of limiting payments to cost for pubic providers. The commenters argued that the statutory restrictions only apply to States' expenditures. Therefore when a State makes a payment for Medicaid covered services, it is that payment by the State which is recognized as the medical assistance expenditure for which Federal matching is made and not the provider's expenditures in rendering the services. The commenters further stated that Congress has never attempted to legislate what a health care provider can do with its Medicaid payments once they have been earned for services rendered. Further, the commenters stated that Congress has never precluded health care providers from using Medicaid revenues to care for the uninsured and Congress did not intend there to be exclusive sources of funding that health care providers could use for covering services to the uninsured.

109R. Response: We agree that allowable Medicaid payments made to a health care provider belong to the health care provider. Through this regulation, however, we intended to provide that a quality of an allowable Medicaid payment is that the health care provider receive and retain the payment for its own purposes, rather than returning it or diverting it for other purposes. Because this may not have been clear, we have revised § 447.207 to make that distinction clear. The provision at § 447.207 was intended to address those instances in which States make claims that are based on health care provider payments that are never actually made, are based on amounts paid with such conditions that the health care provider never actually becomes the beneficial owner of the funding (for example, when the health care provider is required to return the funding to a State agency or State directed purpose), or are otherwise diverted from use for Medicaid services by operation of law, contract or other mechanism. When the health care provider is not permitted to receive and retain the funds, the regulation would reflect the fact that the provider is not the beneficial owner of the funds. It should be noted that the Federal Medicaid statute does not include a term nor discussion that references a ''public'' health care provider for purposes of State Medicaid financing.

110C. Comment: A few commenters expressed concern that the cost limit could affect current DSH calculations and requested clarification. Several other commenters stated that the proposed cost limit would not appear to impact the manner in which several States currently calculate Medicaid DSH payments. Many States' DSH payments are prospectively established using a prior year base period trended forward to the DSH payment period and represent the unreimbursed costs of the uninsured and Medicaid HMO enrollees. The commenters questioned whether the proposed cost limit will require States to annually review the actual unreimbursed costs of the uninsured and Medicaid HMO enrollees of DSH hospitals operated by units of government to ensure that the Medicaid DSH payments did not exceed the actual costs of providing inpatient and outpatient hospital services during the DSH payment period. If so, then the proposed regulation should be modified to allow for the consistent application of a prospective DSH payment methodology.

110R. Response: The provisions of the regulation would require an examination of Medicaid HMO revenues to determine compliance with the Medicaid cost limit, but would not require an examination of the uninsured costs for purposes of the Medicaid cost limit.

The Medicaid cost limit provision is consistent with the statutory establishment of the hospital specific DSH limit, enacted under the Omnibus Budget Reconciliation Act of 1993 (OBRA '93). DSH payments are limited to each qualifying hospital's uncompensated care costs of providing inpatient and outpatient hospital services to Medicaid individuals and to individuals with no source of third party coverage for the inpatient and outpatient hospital services they received. Under the Medicare Modernization Act of 2005 (MMA), Congress enacted DSH audit and reporting requirements to ensure compliance with the OBRA '93 hospital-specific DSH limits. For purposes of DSH payments, States may utilize a prospective DSH payment methodology, but need to ensure actual DSH payments do not exceed actual eligible DSH costs under the hospital-specific limit consistent with OBRA '93 and the MMA. It should be noted that HMO revenues must be considered in the calculation of the hospital-specific DSH limit.

111C. Comment: Several commenters requested that CMS clarify that the cost limit based on the ''cost of providing covered Medicaid services to eligible Medicaid recipients'' does not exclude costs for disproportionate share hospital payments. The commenters were concerned that proposed § 447.206(c)(1) specifies that ''all health care providers that are operated by units of government are limited to reimbursement not in excess of the individual provider's cost of providing covered Medicaid services to eligible Medicaid recipients.'' The commenters believed this would preclude any Medicaid reimbursement to governmental providers for costs of care for patients who are not eligible Medicaid individuals.

The commenters questioned whether it is CMS' intent to either (1) apply the cost limit only to fee-for-service payments by the state agency for services provided to Medicaid individuals while relying on separate statutory or waiver-based authority to impose cost limits on DSH, or (2) to apply the cost limit more broadly than the language of the proposed regulation would suggest. If the limit is to apply only to fee-for-service rates, then DSH should be explicitly exempted. If the limit is to be more broadly applied, then costs for the uninsured or non-covered Medicaid services for purposes of DSH payments must be included. CMS should also clarify that the limitation to cost of Medicaid services for Medicaid individuals is not intended to limit Medicaid DSH payments.

111R. Response: We have modified the regulation to clarify that the Medicaid cost limit provision does not directly apply to DSH payments. Non-Medicaid costs should not be included in the calculation of the Medicaid cost limit. The Medicaid cost limit provision is consistent with the statutory establishment of the hospital specific DSH limit, enacted under the Omnibus Budget Reconciliation Act of 1993 (OBRA '93). DSH payments are limited to each qualifying hospital's uncompensated care costs of providing inpatient and outpatient hospital services to Medicaid individuals and to individuals with no source of third party coverage for the inpatient and outpatient hospital services they received. Under the Medicare Modernization Act of 2005 (MMA), Congress enacted DSH audit and reporting requirements to ensure compliance with the OBRA '93 hospital-specific DSH limits. For purposes of DSH payments, States may utilize a prospective DSH payment methodology, but need to ensure actual DSH payments do not exceed actual eligible DSH costs under the hospital-specific limit consistent with OBRA '93 and MMA.

112C. Comment: A few commenters stated that the cost limit would have a devastating effect on hospitals in low DSH States. The commenters indicated that the adequacy of DSH allotments is declining as costs climb and insurance coverage drops. As DSH has fallen behind, other types of supplemental

payments have become an even more important source of support for these safety net hospitals in low DSH States. If these non-DSH supplemental payments are eliminated, the ability of governmental hospitals to continue to provide high volumes of care to the uninsured will be undermined. Still other commenters stated that the proposed cost limit would cause DSH funds to be distributed away from private hospitals to cover increased losses in public hospitals.

112R. Response: Under the cost limit of the regulation, Medicaid will continue to be permitted to pay for its share of costs associated with a governmentally-operated health care provider's services that benefit Medicaid individuals in accordance with applicable statutory and regulatory requirements. However, when Medicaid is viewed as a primary source of revenue for a government's non-Medicaid activities, no matter how noble such activities may be, the statutory purpose of the Medicaid program has been undermined.

We note that the Congress has expressly provided for certain kinds of limited Federal participation in the costs of providing services to non-Medicaid individuals and public health activities. Examples of limited Congressional authorization of Federal financing for non-Medicaid individuals and public health activities include the following. The Congress authorized disproportionate share hospital (DSH) payments to assist hospitals that serve a disproportionate share of low income individuals which may include hospitals that furnish significant amounts of inpatient hospital services and outpatient hospital services to individuals with no source of third party coverage (that is, the uninsured). Under section 4723 of the Balanced Budget Act of 1997, the Congress also provided direct funding to the States to offset expenditures on behalf of aliens. Additional funding for payments to eligible health care providers for emergency health services to undocumented aliens was also provided by Congress under Section 1011 of the Medicare Modernization Act. The Congress has periodically, and as recently as the Deficit Reduction Act of 2005 (DRA, Pub. L. 109–171, enacted on February 8, 2006), adjusted FMAPs for certain States and certain activities such as an enhanced FMAP to create incentives for States to assist individuals in institutions return to their homes. These examples are provided to illustrate that the Congress has previously authorized limited Federal financing of non-Medicaid individuals and public health activities, but has not to date authorized wider use of Federal Medicaid funding for these purposes. Indeed, the Congress indicated that Medicaid funding was not to be used for non-Medicaid purposes when in the Balanced Budget Act of 1997 (BBA, Pub.L.105–33, enacted on August 5, 1997), it added section 1903(i)(17) to the Act to prohibit the use of FFP ''with respect to any amount expended for roads, bridges, stadiums, or any other item or service not covered under a State plan under this title.'' Non-Medicaid individuals and non-Medicaid services simply are not eligible for Federal reimbursements except where expressly provided for by the Congress.

The Medicaid cost limit provision of the regulation will ensure that governmentally-operated health care providers may receive up to 100 percent of the cost of serving Medicaid individuals, while non-Medicaid costs to the governmentally-operated health care provider will be more appropriately borne by those who are obligated to finance non-Medicaid costs.

113C. Comment: Several other commenters are concerned that since proposed § 447.206 is applicable to DSH payments, DSH payments could then not exceed the cost of services to Medicaid individuals. The commenters argued that then DSH payments could not reflect a hospital's uncompensated costs of care rendered to uninsured individuals and this would be in direct conflict with sections 1902(a)(13)(A) and 1923(g) of the Act. The commenters requested that DSH payments be expressly excluded from the proposed cost limit. In addition, other commenters stated that any willing government entity should have the ability to pay for the non-federal share of DSH payments through either IGTs or CPEs.

113R. Response: We have modified the regulation text to clarify that the Medicaid cost limit provision does not directly apply to DSH payments. The Medicaid cost limit provision is consistent with the statutory establishment of the hospital specific DSH limit, enacted under the Omnibus Budget Reconciliation Act of 1993 (OBRA '93). DSH payments are limited to each qualifying hospital's uncompensated care costs of providing inpatient and outpatient hospital services to Medicaid individuals and to individuals with no source of third party coverage for the inpatient and outpatient hospital services they received. Under the Medicare Modernization Act of 2005 (MMA), Congress enacted DSH audit and reporting requirements to ensure compliance with the OBRA '93 hospital-specific DSH limits. Finally, governmentally-operated health care providers are eligible to participate in IGTs and/or CPEs consistent with section 1903(w)(6)(A) of the Act.

Although there is already an exception for DSH payments in § 447.272(c)(2), we have made other conforming changes. Sections 447.206(c) and 447.321(c) have been modified to include express exceptions to exclude DSH payments from the determination of the individual health care provider's cost of providing covered Medicaid services to eligible Medicaid individuals.

114C. Comment: One commenter noted that if a governmentally operated health care provider is reimbursed its full Medicaid costs, only the unreimbursed costs associated with the uninsured will be used to calculate its allowable DSH payment. The commenter urged CMS to maintain the current method of determining DSH payments.

114R. Response: The Medicaid cost limit provision is consistent with the statutory establishment of the hospital specific DSH limit, enacted under the Omnibus Budget Reconciliation Act of 1993 (OBRA '93). DSH payments are limited to each qualifying hospital's uncompensated care costs of providing inpatient and outpatient hospital services to Medicaid individuals and to individuals with no source of third party coverage for the inpatient and outpatient hospital services they received. Under the Medicare Modernization Act of 2005 (MMA), Congress enacted DSH audit and reporting requirements to ensure compliance with the OBRA '93 hospital-specific DSH limits.

115C. Comment: One commenter requested clarification on how this proposed cost limit impacts health care providers who provide services at no charge, but are allowed to bill Medicaid for such services. The commenter specifically asked whether the provisions of the regulation prevent a health care provider from billing Medicaid for those services the health care provider generally provides at no charge or generally provides to low-income individuals at no charge.

115R. Response: The provisions of this regulation do not impact those policies.

116C. Comment: A few commenters expressed concern with the impact the proposed cost limit would have on payments to federally qualified health centers (FQHCs) and rural health clinics (RHCs). Section 1902(bb) of the Act

requires States to pay for services provided by FQHCs and RHCs through rates that are prospectively determined (based on historical costs). Reimbursement to these types of entities has evolved over the years away from cost reimbursement and towards a prospective payment system that encourages efficiency. This was Congress's explicit direction. The proposed cost limit is in direct conflict with section 1902(bb) of the Act. Other commenters requested clarification that FQHCs are entitled to receive reimbursement through their prospective payment rates in accordance with the statute. Other commenters recommended that the final regulation clarify that FQHCs and RHCs be exempt from the cost settlement requirements.

116R. Response: The commenters correctly noted that section 1902(bb) of the Act requires States to pay for services provided by FQHCs and RHCs through rates that are prospectively determined, based on a base year trended forward according to the Medicare Economic Index. Most FQHCs and RHCs are not governmentally operated. However, based on the statutory provision cited above, in order to address limited instances where the FQHC or RHC may be governmentally operated, we are amending the ''exceptions'' paragraph of the proposed Medicaid cost limit at § 447.206(b) to exempt FQHCs and RHCs from the cost limit.

117C. Comment: Several commenters requested that the proposed cost limit only apply to institutional governmental health care providers and not professional health care providers that may be employed by or affiliated with governmental entities. The commenters state that while the proposed regulation is clear that the limit applies not just to hospital and nursing facility providers, but also to ''non-hospital and non-nursing facility services'', it is unclear beyond this the scope of the term ''provider.'' The commenter asked whether the cost limit extends to professionals employed by governmental entities. These commenters request that the proposed regulation not be extended this far, as cost-based methodologies are particularly inappropriate for professional services. Another commenter stated that if the cost limit does apply to professional providers, it is unclear how to determine whether such providers are an ''integral part'' of a unit of government or are ''operated by'' a unit of government. A cost limit would be inappropriate for professional services, and the commenter urges CMS not to apply the cost limit provisions to professionals. One commenter requested additional clarification that CPEs can be made for physicians, which are not subject to cost based reimbursement methodologies.

117R. Response: The proposed cost limit applies to all governmentally-operated Medicaid health care providers, including governmentally-operated entities that are paid by the State as health care providers for professional services. Whether or not a specific health care provider is subject to the Medicaid cost limit will depend on whether or not the health care provider is considered a unit of government under § 433.50. CMS recognizes that legal and financial arrangements between health care providers and units of government vary on a case by case basis. Therefore, CMS has developed standardized and impartial regulatory criteria based upon Federal statute that States must apply on a consistent basis to each health care provider within the State to make initial determinations of governmental status. Finally, we note that individual physicians can be involved in CPE practices only indirectly; if they are paid by a unit of government able to participate in Medicaid financing, that unit of government can claim a CPE for actual payments that are consistent with the payment methods under the approved Medicaid State plan.

118C. Comment: One commenter stated that they have an approved Medicaid supplemental payment for ambulance services, and the commenter specifically requested that the cost limit should not be applied to ambulance services. The commenter stipulated that Medicare would not include ambulance services for purposes of cost-based reimbursement, as ambulance services are reimbursed by Medicare through a fee schedule.

118R. Response: The proposed cost limit applies to all governmentally-operated Medicaid health care providers, including ambulance providers. Whether or not a specific health care provider is subject to the Medicaid cost limit will depend on whether or not the health care provider is considered a unit of government under § 433.50. There is no statutory or regulatory basis to require Medicaid reimbursement policy for the provision of ambulance services to follow Medicare reimbursement policy for such services.

119C. Comment: Several commenters were concerned that by limiting payments to providers, including physical therapists, trauma care, neonatal intensive care, emergency physicians and departments, burn units, many of these health care providers will be forced to significantly reduce the number of Medicaid individuals that they treat and may in fact choose to withdraw their enrollment from the Medicaid program completely. Other commenters stated that Medicaid reimbursement rates in a majority of the States are already very low in comparison to Medicare and private insurers. Another commenter stated that as fewer physicians accept Medicaid, more and more Medicaid individuals will end up in Emergency Room Departments, leading to what the recent Institute of Medicine report on the future of emergency care predicts is an over crossed emergency care system staggering under growing levels of uncompensated physician and hospital care. One commenter stated that such a policy would endanger the ability of public hospitals to ensure quality and patient safety and maintain vital and irreplaceable community services. Other commenters were concerned that the proposed cost limit will be harmful to the continuing viability of the range of services available to seriously mentally ill adults and children living in our communities. Another commenter noted that because States with public hospitals will likely favor their public hospitals in the distribution of available resources, the commenter believed that reducing the overall pool of resources available to States would end up hurting private, non-profit safety-net hospitals. Other commenters indicated that the proposed regulation will prohibit the ability of States to sufficiently fund their portion of Medicaid matching funds, effectively limiting the delivery of necessary healthcare services to low-income Americans. Finally, one commenter recommended that the proposed regulation be modified to limit all Medicaid reimbursements to a hospital's cost of care serving Medicaid and uninsured individuals, regardless of whether the facility is deemed to be a unit of government.

119R. Response: CMS agrees that Medicaid is a vitally important program that serves very vulnerable individuals, and the Federal government remains committed to funding its share of the cost of providing Medicaid services to eligible individuals. Many of the expressed concerns about the potential impact of the cost limit are overstated. Under the provisions of the regulation, governmentally-operated health care providers will be permitted to receive up to 100 percent of the cost of serving Medicaid individuals. It does not appear that limiting Medicaid reimbursement

to the full cost or providing services to Medicaid individuals would adversely affect a governmentally-operated health care provider, unless the health care provider had been historically receiving Medicaid payments above cost and using excess Medicaid revenues to subsidize other costs outside of the Medicaid program. In such a situation, the proposed cost limit could cause a net reduction in Medicaid revenue to the health care provider, but the amount of the reduction would directly correspond with the amount of Medicaid revenues that had been used for non-Medicaid purposes. Governmentally-operated health care providers not receiving Medicaid payments in excess of costs, would not be adversely impacted by the Medicaid cost limit and would actually be eligible to receive greater Medicaid revenues, up to the cost limit. In either case, the cost limit provision should not force health care providers to reduce the number of Medicaid individuals they treat or withdraw from the Medicaid program.

Non-governmentally-operated health care providers, including many of the ''public'' safety net health care providers, are *not* affected by the cost limit provision of the regulation and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements. It remains unclear how a limit that does not apply to public hospitals could adversely impact quality and patient safety and vital community services.

Moreover, the provisions of the regulation reaffirms State Medicaid financing policy requiring that health care providers be allowed to fully retain their Medicaid payments, another provision of which clearly demonstrates the Federal government's intent to protect the nation's public safety net and its ability to continue delivering critical health care services to Medicaid individuals and the uninsured. Any health care providers that become ineligible to participate in the State financing of Medicaid payments following the effective date of the provisions of this regulation can realize greater net revenues if State or local government funding sources are utilized to fund non-Federal share obligations to Medicaid payments historically financed by non-governmentally-operated ''public'' health care providers.

120C. Comment: Numerous commenters argued that governmental health care providers, who disproportionately serve the uninsured, should not be subject to a more restrictive limit than private health care providers. Imposing such a limit would undermine important policy goals, including quality, patient safety, emergency preparedness, enhancing access to primary and preventive care, reducing costly and inappropriate use of hospital emergency rooms, adoption of electronic medical records and reducing health disparities, shared by the Administration and health care providers. Further, the commenters noted that in the heightened security-conscious post-9/11 world, public hospitals play a critical role in local emergency preparedness efforts, enhancing their readiness to combat both manmade and natural disasters and epidemics. The commenters do not believe that CMS considered the impact of the cost limit on shared policy initiatives that HHS itself has established as key goals of America's complex health care system.

120R. Response: We understand that governmentally-operated health care providers have numerous goals and objectives that extend beyond the Medicaid program and that Medicaid individuals may ultimately benefit from the governmentally-operated health care provider's broader activities. Under the cost limit of the regulation, Medicaid will continue to be permitted to pay for its share of costs associated with a governmentally-operated health care provider's services that benefit Medicaid individuals in accordance with applicable statutory and regulatory requirements. However, when Medicaid is viewed as a primary source of revenue for a government's non-Medicaid activities, no matter how noble such activities may be, the statutory purpose of the Medicaid program has been undermined.

We note that the Congress has expressly provided for certain kinds of limited Federal participation in the costs of providing services to non-Medicaid individuals and public health activities. Examples of limited Congressional authorization of Federal financing for non-Medicaid individuals and public health activities include the following. The Congress authorized disproportionate share hospital (DSH) payments to assist hospitals that serve a disproportionate share of low income individuals which may include hospitals that furnish significant amounts of inpatient hospital services and outpatient hospital services to individuals with no source of third party coverage (that is, the uninsured). Under section 4723 of the Balanced Budget Act of 1997, the Congress also provided direct funding to the States to offset expenditures on behalf of aliens. Additional funding for payments to eligible health care providers for emergency health services to undocumented aliens was also provided by Congress under Section 1011 of the Medicare Modernization Act. The Congress has periodically, and as recently as the Deficit Reduction Act of 2005 (DRA, Pub. L. 109–171, enacted on February 8, 2006), adjusted FMAPs for certain States and certain activities such as an enhanced FMAP to create incentives for States to assist individuals in institutions return to their homes. These examples are provided to illustrate that the Congress has previously authorized limited Federal financing of non-Medicaid individuals and public health activities, but has not to date authorized wider use of Federal Medicaid funding for these purposes. Indeed, the Congress indicated that Medicaid funding was not to be used for non-Medicaid purposes when in the Balanced Budget Act of 1997 (BBA, Pub.L.105–33, enacted on August 5, 1997), it added section 1903(i)(17) to the Act to prohibit the use of FFP ''with respect to any amount expended for roads, bridges, stadiums, or any other item or service not covered under a State plan under this title.'' Non-Medicaid individuals and non-Medicaid services simply are not eligible for Federal reimbursements except where expressly provided for by the Congress.

The Medicaid cost limit provision of the regulation will ensure that governmentally-operated health care providers may receive up to 100 percent of the cost of serving Medicaid individuals, while non-Medicaid costs to the governmentally-operated health care provider will be more appropriately borne by those who are obliged to finance non-Medicaid costs.

121C. Comment: A few commenters stated their concern that the proposed regulation could adversely affect inpatient capacity and community access to vital services, such as trauma centers, at a time when the Nation is faced with significant threats to the public. One commenter stated that if this proposed regulation is allowed to be implemented many individuals, including children, the working poor, and the elderly will no longer be able to obtain needed health care services. Several commenters indicated that they will be forced to make cuts to the Medicaid program that would affect participant eligibility and a reduction in benefits and services provided. Another commenter was concerned that as health care providers cut back on the number of uninsured they can treat, these individuals will go to health centers, which have already realized a

128 percent increase in number of uninsured treated over the past fifteen years, thus overwhelming their critical safety net.

121R. Response: CMS agrees that Medicaid is a vitally important program that serves very vulnerable individuals, and the Federal government remains committed to funding its share of the cost of providing Medicaid services to eligible individuals. Many of the expressed concerns about the potential impact of the cost limit are overstated. Under the provisions of the regulation, governmentally-operated health care providers will be permitted to receive up to 100 percent of the cost of serving Medicaid individuals. It does not appear that limiting Medicaid reimbursement to the full cost of providing services to Medicaid individuals would adversely impact a governmentally-operated health care provider, unless the health care provider had been historically receiving Medicaid payments above cost and using excess Medicaid revenues to subsidize costs outside of the Medicaid program. In such a situation, the proposed cost limit could cause a net reduction in Medicaid revenue to the health care provider, but the amount of the reduction would directly correspond with the amount of Medicaid revenues that had been used for non-Medicaid purposes. Governmentally-operated health care providers not receiving Medicaid payments in excess of costs would not be adversely impacted by the cost limit and would actually be eligible to receive greater Medicaid revenues up to the cost limit. In either case, the cost limit provision should not force cuts to the Medicaid program, nor affect eligibility, benefits and services.

Non-governmentally-operated health care providers, including many of the ''public'' safety net hospitals, are *not* affected by the cost limit provision of the regulation and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements. It is unclear how a limit that does not apply to public hospitals would reduce services or limit access to Medicaid individuals or to the uninsured.

Moreover, the provision of the regulation that requires that health care providers be allowed to fully retain their Medicaid payments demonstrates the Federal government's intent to protect the nation's public safety net and its ability to continue delivering critical health care services to Medicaid individuals and the uninsured. This ensures that the full amount of Medicaid payment is available to support services to this vulnerable population. Moreover, health care providers that become ineligible to participate in financing of Medicaid payments following the effective date of the provisions of this regulation can realize greater net revenues if State or local government funding sources are utilized to fund non-Federal share obligations to Medicaid payments historically financed by non-governmentally-operated ''public'' health care providers.

122C. Comment: A couple of commenters were concerned that as the Medicaid program is streamlined to become more efficient and cost-effective, optional services, such as physical therapy will be marginalized. The commenters stated that elimination of such services could lead to more institutionalized care and the development of more severe health conditions.

122R. Response: Optional services, like physical therapy, which tend to reduce institutionalized care and prevent more severe health conditions, should not be at risk of being eliminated as the Medicaid program becomes more efficient and cost effective. On the contrary, optional services that are preventative in nature would be increasingly desirable in an efficient and cost-effective health care delivery system. Nevertheless, decisions about coverage of optional services are made by the States, and the Federal government will continue to match State expenditures for such services as long as they are an approved part of the State's Medicaid program consistent with all applicable Federal statutory and regulatory requirements.

123C. Comment: Numerous commenters pointed out that by prohibiting payments of costs other than the marginal expenses associated with treating Medicaid individuals, public providers will be uncompensated for the range of costs that underlie the delivery of healthcare to this vulnerable population. Other commenters stipulated that the Medicaid statue does not equate cost with efficiency, economy and quality of care and there are a number of points to indicate that payments in excess of an individual provider's cost may still be appropriate for a State's Medicaid program overall. Section 1902(a)(30)(A) of the Act requires that Medicaid payment be sufficient to enlist enough health care providers so that care and services are available to Medicaid individuals. The commenters specified that health care providers who rely most on Medicaid payments are typically those who also have high Medicare and charity care patient use. Therefore the proposed cost limit would severely limit their ability to generate the margins necessary to operate effectively, replace or add to capital assets, and plan for growth, thus resulting in a reduction in the amount of services offered. In addition, the commenters stated that DSH payments are inadequate in covering the cost of charity care and providing for any margin on Medicaid services.

Other commenters stated that health care providers cannot survive without positive operating margins. Any well-run business needs to achieve some margin in order to invest in the future, establish a prudent reserve fund, and achieve the stability which will allow it access to needed capital. Particularly in public hospitals, margins on Medicare and commercial insurance alone are not sufficient to keep public hospitals solvent. Various commenters stated examples of levels of Medicaid and uninsured in public health care providers. One commenter noted that Medicare and commercial insurance amount to less than 45 percent of public hospitals' average net revenues, while self-pay individuals comprise 24 percent of the population served in those hospitals. Therefore the commenters believed it is unfair to expect these health care providers, with their disproportionate share of uninsured populations to survive and thrive.

Many commenters stated that States traditionally pay limited numbers of health care providers more than their Medicaid costs. Those health care providers that do receive payments above cost are located in areas where, in addition to caring for large numbers of Medicaid individuals, they also care for large numbers of uninsured individuals and without such payments the financial viability of these providers would be in jeopardy. These providers would be unable to serve all of their patients. These commenters believe it is entirely appropriate for Medicaid programs to pay some health care providers more than their costs. Hospitals that care for large numbers of Medicaid individuals inevitably care for larger numbers of uninsured individuals as well. Several health care providers also commented on the amount of supplemental Medicaid funding they receive and the fact that those payments are critical to their ability to serve as a health care safety net provider in their respective communities.

Numerous other commenters pointed out all of the activities that health care providers use supplemental Medicaid payments to support are in fact integrally related to Medicaid. The commenters were disturbed that CMS

made allegations that these payments were not in fact used for Medicaid purposes. For example, one health care provider indicated that ensuring a strong emergency response capability is critical to ensuring that Medicaid individuals can receive care when needed. Another commenter indicated that their Medicaid payments above cost help offset other uncompensated costs, including physician staffing, costs of serving indigent patients, bad debt, etc. All of these commenters stated that these payments are critical to ensure adequate access. Other commenters noted these supplemental Medicaid payments above cost were approved by CMS through State plan amendments.

123R. Response: CMS agrees that Medicaid is a vitally important program that serves very vulnerable populations, and the Federal government remains committed to funding its share of the cost of providing Medicaid services to eligible individuals. By providing for the ability to pay government providers the full cost of Medicaid services, we are recognizing that States may contribute a fair share of all costs necessary to operate the provider, including the costs of capital assets, strategic planning for growth, and other necessary administrative activities.

Further, we understand that governmentally-operated health care providers have numerous goals and objectives that extend beyond the Medicaid program and that Medicaid individuals may ultimately benefit from the governmentally-operated health care provider's broader activities. Under the cost limit of the regulation, Medicaid will continue to be permitted to pay for its share of costs associated with a governmentally-operated health care provider's services that benefit Medicaid individuals in accordance with applicable statutory and regulatory requirements. However, when Medicaid is viewed as a primary source of revenue for a government's non-Medicaid activities, no matter how noble such activities may be, the statutory purpose of the Medicaid program has been undermined. We note that the Congress has expressly provided for certain kinds of limited Federal participation in the costs of providing services to non-Medicaid individuals and public health activities. Examples of limited Congressional authorization of Federal financing for non-Medicaid individuals and public health activities include the following. The Congress authorized disproportionate share hospital (DSH) payments to assist hospitals that serve a disproportionate share of low income individuals which may include hospitals that furnish significant amounts of inpatient hospital services and outpatient hospital services to individuals with no source of third party coverage (that is, the uninsured). Under section 4723 of the Balanced Budget Act of 1997, the Congress also provided direct funding to the States to offset expenditures on behalf of aliens. Additional funding for payments to eligible health care providers for emergency health services to undocumented aliens was also provided by Congress under Section 1011 of the Medicare Modernization Act. The Congress has periodically, and as recently as the Deficit Reduction Act of 2005 (DRA, Pub. L. 109–171, enacted on February 8, 2006), adjusted FMAPs for certain States and certain activities such as an enhanced FMAP to create incentives for States to assist individuals in institutions return to their homes. These examples are provided to illustrate that the Congress has previously authorized limited Federal financing of non-Medicaid individuals and public health activities, but has not to date authorized wider use of Federal Medicaid funding for these purposes. Indeed, the Congress indicated that Medicaid funding was not to be used for non-Medicaid purposes when in the Balanced Budget Act of 1997 (BBA, Pub. L. 105–33, enacted on August 5, 1997), it added section 1903(i)(17) to the Act to prohibit the use of FFP ''with respect to any amount expended for roads, bridges, stadiums, or any other item or service not covered under a State plan under this title.'' Non-Medicaid individuals and non-Medicaid services simply are not eligible for Federal reimbursements except where expressly provided for by the Congress.

Additionally, many of the expressed concerns about the potential impact of the cost limit are overstated. Under the provisions of the regulation, governmentally-operated health care providers will be permitted to receive up to 100 percent of the cost of serving Medicaid individuals. We do not agree that an allowance for payments up to cost would violate the provision of section 1902(a)(30)(A) of the Act which requires that Medicaid payment be sufficient to enlist enough health care providers so that care and services are available to Medicaid individuals because all of the health care provider's Medicaid costs can be satisfied. We are unclear how limiting Medicaid reimbursement to the full cost of providing services to Medicaid individuals would adversely affect a governmentally-operated health care provider, unless as some commenters note, the health care provider had been historically receiving Medicaid payments above cost and using excess Medicaid revenues to subsidize costs outside of the Medicaid program. In such a situation, the proposed cost limit could cause a net reduction in Medicaid revenue to the health care provider, but the amount of the reduction would directly correspond with the amount of Medicaid revenues that had been used for non-Medicaid purposes. We do not believe Medicaid is responsible to the profit margins of governmentally-operated health care providers and question the appropriateness of such a suggestion.

Non-governmentally-operated health care providers, including many of the ''public'' safety net hospitals referenced by the commenters, are *not* affected by the cost limit provision of the regulation and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements. It is unclear how a limit that does not apply to non-governmentally-operated ''public'' health care providers could adversely impact the financial viability of safety net health care providers or access to care for Medicaid and uninsured individuals.

Moreover, one provision of the regulation reaffirms State Medicaid financing policy requiring that health care providers be allowed to fully retain their Medicaid payments, another provision of which clearly demonstrates the Federal government's intent to protect the nation's public safety net and its ability to continue delivering critical health care services to Medicaid individuals and the uninsured. Any health care providers that become ineligible to participate in the State financing of Medicaid payments following the effective date of the provisions of this regulation can realize greater net revenues if State or local government funding sources are utilized to fund non-Federal share obligations to Medicaid payments historically financed by non-governmentally-operated ''public'' health care providers.

124C. Comment: Many commenters stated that cost-based payments and limits are inherently inefficient by rewarding providers with high costs. Commenters pointed out that prospective payment systems are structured to encourage health care providers to eliminate excess costs by allowing them to keep payments above costs as a reward for efficiency. A payment limit based on costs represents a sharp departure from CMS' efforts to

bring cost-effective market principles into federal health programs. Rather, this proposed cost limit would incentivize health care providers to increase costs and eschew efficiencies in order to preserve revenues.

A few other commenters noted that a return to cost-based reimbursement for public providers will permit them to break even at best, while permitting costs to spiral upwards. These commenters urged CMS to proceed with the development of innovative ways to reimburse providers as opposed to reverting solely to cost based methodologies.

124R. Response: This rule does not require cost based paymnt methodologies; States have flexibility to use any payment methodology that results in payment levels that do not exceed provider cost. To the extent that a State elects a cost based payment methodology, that method would be limited to government providers that, by their nature, are not seeking profit and have a high degree of public accountability. As a result, we do not believe the Medicaid cost limit will give incentives to health care providers to increase costs. Moreover, because we are strengthening the integrity of the funding of the non-federal share of expenditures, our State and local partners will play a role in controlling excessive costs at government providers.

The Medicare cost allocation process utilized for institutional health care providers is considered a key component in determining Medicaid cost under the provisions of the regulation. Institutional governmentally-operated health care providers (*i.e.*, hospitals (encompassing both inpatient and outpatient hospital services, nursing facilities, and intermediate care facilities for the mentally retarded (ICFs/MR)) will be required to provide the State with data extracted from primary source documents as well as copies of the source documents. These documents would include the governmentally-operated health care provider's Medicare cost report (or Medicaid cost report for intermediate nursing facility care and ICFs/MR consistent with Medicare cost reporting principles), and audited financial statements that will be used in conjunction with information provided by the States' Medicaid Management Information Systems (MMIS).

For non-institutional services provided to Medicaid eligible individuals, a nationally recognized, standard cost report does not currently exist. Because of this, we intend to publish a standardized cost reporting form to document the cost of such services. The purpose of this standardized form is to document in a uniform manner the cost of providing non-institutional services to Medicaid individuals. The period of time to which this cost report applies will be the Medicaid State plan rate year.

CMS has developed a general Medicaid Cost Reporting Protocol that will be on the CMS website that specifically addresses the methods under which institutional and non-institutional Medicaid costs will be determined. The protocol was designed to provide States with detailed instructions to determine compliance with Federal requirements.

Finally, it is important to note that non-governmentally-operated health care providers, including many of the ''public'' safety net health care providers referenced by the commenters, are not affected by the Medicaid cost limit provision of the regulation and may, therefore, continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements.

125C. Comment: Numerous commenters stated that the proposed cost limit would impose enormous new administrative burdens on States and health care providers, since cost reconciliation processes could last for years beyond when services are provided. These commenters argued since this will have no impact on the quality or effectiveness of care provided to individuals, these requirements should be eliminated. Further, the precision gained by reconciling payments to actual costs for the payment year as determined by a finalized cost report is not worth the massive diversion of resources. The commenters recommended that CMS revise the proposed regulation to allow States to calculate the cost limit on a prospective basis and allow States to invest the savings in services that will benefit patients.

125R. Response: We do not believe the cost limit will impose significant administrative burden on States particularly since such limit applies only to governmentally-operated health care providers.

For purposes of institutional governmentally-operated health care providers, the Medicaid cost limit determination will rely on existing reporting tools used by institutional health care providers. States will not be required to audit financial and cost information provided by individual institutional governmentally-operated health care providers as part of the Medicaid cost limit review. Each of the source documents is subject to reporting and auditing rules specific to the original purpose of that document and independent of the Medicaid cost limit and State review process. The State must render an determination on the cost limit methodology applied to the source documents but will not be required to validate the accuracy of the information and data within the source documents.

For non-institutional services provided to Medicaid eligible individuals, we note that a nationally recognized, standard cost report does not exist. Because of this, we intend to publish a standardized cost reporting form to document the cost of such services. The purpose of this standardized form is to document in a uniform manner the cost of providing non-institutional services to Medicaid individuals. The period of time to which this cost report applies will be the Medicaid State plan rate year.

CMS has modified the regulation to include a transition period to allow States and governmentally operated non-institutional health care providers sufficient time to develop and implement Medicaid cost documentation and reporting processes consistent with the cost report template issued by CMS (including but not limited to changes in State/provider reporting systems, changes to the Medicaid State plan, changes to time studies, establish periodic review and audit processes, etc.), States will not be required to document and report cost information associated with non-institutional Medicaid services until the State's Medicaid State plan rate year 2009. Actual submission of the State's summary report on the Medicaid cost limit for non-institutional services will not be due to CMS until December 31, 2011, which allows States an opportunity to implement periodic review and audit processes for Medicaid non-institutional costs starting in Medicaid State plan rate year 2009.

CMS has developed a general Medicaid Cost Reporting Protocol that will be on the CMS website that specifically addresses the methods under which institutional and non-institutional Medicaid costs will be determined. The protocol was designed to provide States with detailed instructions to determine compliance with Federal requirements.

126C. Comment: A few commenters believe this will create little real benefit to health care providers and will result in substantial administrative burden. They are also concerned these new documentation standards will also subject Medicaid providers to

unwarranted allegations of False Claims Act violations. These commenters take their obligations to report Medicaid expenditures properly and believe that because of this, CMS can ensure the accuracy of Medicaid claims without imposing burdensome certification requirement. Another commenter questioned how the administrative burden would be minimized. Another commenter stated that CMS is requiring States to implement interim rate methodologies with retrospective determination of whether the payments exceeded the provider's cost to provide the services. Development and implementation of these processes for providers, States and units of government will result in significantly increased administrative and auditing workloads.

126R. Response: We agree with the commenters that most Medicaid health care providers take seriously their obligations to report Medicaid expenditures properly. While we recognize that increased efforts in cost reporting will increase fiscal accountability among units of government involved in the delivery of Medicaid services, we do not believe that this will produce a disproportionate number of meritless claims alleging violations of the False Claims Act. Moreover, we do not believe the Medicaid cost limit will impose significant administrative burden on States particularly since such limit applies only to governmentally-operated health care providers.

For purposes of institutional governmentally-operated health care providers, the Medicaid cost limit determination will rely on existing cost reporting tools used by institutional health care providers. States will not be required to audit financial and cost information provided by individual institutional governmentally-operated health care providers as part of the Medicaid cost limit review. Each of the source documents is subject to reporting and auditing rules specific to the original purpose of that document and independent of the Medicaid cost limit and State review process. The State must render an determination on the cost limit methodology applied to the source documents but will not be required to validate the accuracy of the information and data within the source documents.

For non-institutional services provided to Medicaid eligible individuals, we note that a nationally recognized, standard cost report does not exist. Because of this, we are publishing a standardized cost reporting form to document the costs of such services. The purpose of this standardized form is to document in a uniform manner the cost of providing non-institutional services to Medicaid individuals. The period of time to which this cost report applies will be the Medicaid State plan rate year.

CMS has modified the regulation to include a transition period to allow States and governmentally operated non-institutional health care providers sufficient time to develop and implement Medicaid cost documentation and reporting processes consistent with the cost report template issued by CMS (including but not limited to changes in State/provider reporting systems, changes to the Medicaid State plan, changes to time studies, establish periodic review and audit processes, etc.), States will not be required to document and report cost information associated with non-institutional Medicaid services until the State's Medicaid State plan rate year 2009. Actual submission of the State's summary report on the Medicaid cost limit for non-institutional services will not be due to CMS until December 31, 2011, which allows States an opportunity to implement periodic review and audit processes for Medicaid non-institutional costs starting in Medicaid State plan rate year 2009.

CMS has developed a general Medicaid Cost Reporting Protocol that will be on the CMS website that specifically addresses the methods under which institutional and non-institutional Medicaid costs will be determined.

127C. Comment: One commenter indicated that cost reconciliation will be a ''big win'' for consulting companies that specialize in Medicaid and health care data. States short on resources will be forced to pay their high administrative fees to comply with these new requirements.

127R. Response: CMS has developed a general Medicaid Cost Reporting Protocol that will be on the CMS website that specifically addresses the methods under which institutional and non-institutional Medicaid costs will be determined. The protocol was designed to provide States with detailed instructions to determine compliance with the Federal requirements and should not necessarily require the input from entities independent of the State and governmentally-operated health care providers. It is important to note that States must follow the instructional protocol and cannot deviate from such instructions. Determinations made by States that are inconsistent with the Federal requirements could result in disallowance action.

128C. Comment: A few commenters stated that even when cost limits are applied, CMS should reconsider the requirement for interim and final payment rates for all public providers. The commenters indicated that prospective payment rates such as DRG-based payments or case-mix adjusted per diem rates are often below costs. Requiring States to use interim and settle-up payment methodologies adds a costly level of administrative burden and produces no cost savings at all. Further, the commenters noted that savings generated by subjecting cost-based prospective payment rates that are periodically updated for inflation to retrospective reconciliation would not be sufficient to justify the added administrative costs of the reconciliation process.

128R. Response: It is important to note that ''public'' providers are not subject to the Medicaid cost limit. Only governmentally-operated health care providers will be subject to the Medicaid cost limit. Non-governmentally-operated health care providers, including many of the ''public'' safety net hospitals, are not affected by the cost limit provision of the regulation and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements.

The Medicaid cost limit provision neither requires nor precludes interim and final Medicaid payment rates for governmentally-operated health care providers. The Medicaid cost limit provision also does not require States to abandon existing DRG based payment systems or any other existing Medicaid reimbursement rate methodologies currently utilized to pay governmentally-operated health care providers. Under the Medicaid cost limit, States may continue to use existing Medicaid reimbursement rate methodologies, but will need to compare such rates to the actual cost of providing services to Medicaid individuals and make reconciling adjustments in the event of overpayments to a governmentally-operated health care provider. The Medicaid cost limit provision does not require Medicaid payments to be equal to a governmentally-operated health care provider's cost of providing services to Medicaid individuals. The Medicaid cost limit provision instead stipulates that Medicaid payments must be no more than a governmentally-operated health care provider's cost of such services.

129C. Comment: Many commenters stated that because the proposed cost

limit makes all payments received by public providers interim and subject to retrospective reconciliation to costs, this will cause severe financial hardships for public providers. Finally, the commenters indicated that States do not have the necessary administrative procedures and mechanisms in place to conduct the audits and appeals necessary to implement the proposed cost limit.

129R. Response: It is important to note that ''public'' providers are not subject to the Medicaid cost limit. Only governmentally-operated health care providers will be subject to the Medicaid cost limit. Non-governmentally-operated health care providers, including many of the ''public'' safety net health care providers, are *not* affected by the cost limit provision of the regulation and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements.

The Medicaid cost limit provision does not make all payments received by governmentally operated health providers ''interim'' in nature. The Medicaid cost limit provision also does not require States to replace existing Medicaid reimbursement rate methodologies currently utilized to pay governmentally-operated health care providers. Under the Medicaid cost limit, States may continue to use existing Medicaid reimbursement rate methodologies, but will need to compare such rates to the actual cost of providing services to Medicaid individuals and make reconciling adjustments in the event of overpayments to a governmentally operated provider.

The Medicaid cost limit provision does not require Medicaid payments to be equal to a governmentally-operated health care provider's cost of providing services to Medicaid individuals. The Medicaid cost limit provision instead stipulates that Medicaid payments must be no more than a governmentally-operated health care provider's cost for such services.

We do not believe the cost limit will impose significant administrative burden on States particularly since such limit applies only to governmentally-operated health care providers. These providers are governmental partners in providing health care and anticipate that there will be a degree of cooperation in complying with State implementation of these Medicaid requirements.

For purposes of institutional governmentally-operated health care providers, the Medicaid cost limit determination will rely on existing cost reporting tools used by institutional health care providers. States will not be required to audit financial and cost information provided by individual institutional governmentally-operated health care providers as part of the Medicaid cost limit review. Each of the source documents is subject to reporting and auditing rules specific to the original purpose of that document and independent of the Medicaid cost limit and State review process. The State must render a determination on the cost limit methodology applied to the source documents but will not be required to validate the accuracy of the information and data within the source documents.

130C. Comment: One commenter noted that the proposed requirement to develop a cost-based rate for each public provider with cost settlement after the fact is a tremendous financial and administrative burden. The commenter explained that CMS allows States to develop statewide reimbursement methodologies for specific services delivered by public providers and that States often do this through statewide time study methodologies. The commenter indicated that the proposed cost limit would require each provider to develop a cost-based rate for each service which would require individual time studies, necessitating much larger sample sizes and much more extensive data analysis.

130R. Response: It is important to note that ''public'' providers are not subject to the Medicaid cost limit. Only governmentally-operated health care providers will be subject to the cost limit. Non-governmentally-operated health care providers, including many of the ''public'' safety net health care providers referenced by the commenters, are *not* affected by the Medicaid cost limit provision of the regulation and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements.

The Medicaid cost limit provision also does not require the development of a cost-based rate for governmentally-operated health care providers, nor does it require States to abandon existing Medicaid reimbursement rate methodologies currently utilized to pay governmentally-operated health care providers. Under the Medicaid cost limit provision, States may continue to use existing Medicaid reimbursement rate methodologies, but will need to compare such rates to the individual health care provider's actual cost of providing services to Medicaid individuals and make reconciling adjustments in the event of overpayments to a governmentally operated provider.

As important, the cost upper payment limit is provider-specific but it does not require reconciliation of every individual service to cost. Moreover, this regulation would not require time studies or sampling. These methods are used to determine the cost of Medicaid when the provider does not have other methods of establishing the proportion of costs attributable to the Medicaid program. In some circumstances, these methods may be less expensive and more efficient than maintaining detailed records of individual service encounters and patient eligibility.

131C. Comment: One commenter discussed the unique nature of frontier States and the need to purchase a broad range and volume of Medicaid services out-of-state and the increased new workload associated by the provisions of this regulation. This commenter noted that this will require the State to make the cost limit determination through an audit of the unit of government or governmental health provider or monitor and accept the servicing State's cost limit determination and make the retrospectively calculated refund of any overpayment to CMS.

131R. Response: We recognize that certain health care providers deliver services to Medicaid individuals that reside in another State and are reimbursed for those services from other States. Under the Medicaid cost limit provision of the regulation, a governmentally-operated health care provider will not be required to differentiate Medicaid payments received and the Medicaid costs incurred based upon Medicaid individuals' State of residence. For purposes of the Medicaid cost limit, States must consider a governmentally-operated health care provider's total Medicaid revenues received and the total Medicaid costs incurred for providing services to Medicaid individuals, regardless of the State of residence of a specific Medicaid eligible individual. A State is only responsible to ensure compliance with the Medicaid cost limit for the governmentally-operated health care providers located in the State, and not for governmentally-operated health care providers in another State. This approach simplifies the implementation and demonstration of the Medicaid cost limit for States and governmentally-operated providers.

132C. Comment: Many commenters asserted that the proposed cost limit will create an administrative burden on

States and health care providers that will be inefficient, time consuming and redundant. The proposed changes impose onerous reporting and accounting processes to government systems, including schools, which would likely not be beneficial to the end result of a Medicaid payment for the effort required. These commenters urge CMS to eliminate the individual provider cost limit and consider a reasonable measurement to ensure a proper and efficient reimbursement limitation without the unnecessary administrative burden.

132R. Response: We do not believe the Medicaid cost limit will imposes significant administrative burden on States particularly since such limit applies only to governmentally-operated health care providers.

For purposes of institutional governmentally-operated health care providers, the Medicaid cost limit determination will rely on existing reporting tools used by institutional health care providers. States will not be required to audit financial and cost information provided by individual institutional governmentally-operated health care providers as part of the Medicaid cost limit review. Each of the source documents is subject to reporting and auditing rules specific to the original purpose of that document and independent of the Medicaid cost limit and State review process. The State must render a determination on the cost limit methodology applied to the source documents but will not be required to validate the accuracy of the information and data within the source documents.

For non-institutional services provided to Medicaid eligible individuals, a nationally recognized, standard cost report does not currently exist. Because of this, we are publishing a standardized cost reporting form to document the costs of such services. The purpose of this standardized form is to document in a uniform manner the cost of providing non-institutional services to Medicaid individuals. The period of time to which this cost report applies will be the Medicaid State plan rate year.

CMS has modified the regulation to include a transition period to allow States and governmentally operated non-institutional health care providers sufficient time to develop and implement Medicaid cost documentation and reporting processes consistent with the cost report template issued by CMS (including but not limited to changes in State/provider reporting systems, changes to the Medicaid State plan, changes to time studies, establish periodic review and audit processes, etc.), States will not be required to document and report cost information associated with non-institutional Medicaid services until the State's Medicaid State plan rate year 2009. Actual submission of the State's summary report on the Medicaid cost limit for non-institutional services will not be due to CMS until December 31, 2011, which allows States an opportunity to implement periodic review and audit processes for Medicaid non-institutional costs starting in Medicaid State plan rate year 2009.

CMS has developed a general Medicaid Cost Reporting Protocol that will be on the CMS Web site that specifically addresses the methods under which institutional and non-institutional Medicaid costs will be determined.

133C. Comment: Many commenters believe that it is unreasonable to impose a lower limit on Medicaid reimbursements to governmental providers than private providers. Most commenters stated it was unclear why CMS believes that rates we would continue to allow states to pay private providers are excessive with respect to government providers. Another commenter mentioned that public hospitals do not have access to the kind of non-patient care revenues (investment income) that other private hospital systems do.

Other commenters stated that if the proposed cost limit is consistent with section 1902(a)(30)(A) of the Act, then there is no rational basis for distinguishing between public and private providers. Requiring differential treatment of public and private Medicaid providers is inconsistent with the equal protection clause of the Constitution as well as CMS' own repeated statements regarding the importance of payment equality for all categories of Medicaid providers. In fact, in its 2002 final UPL rule CMS agreed that ''one group of providers should not have a financial benefit over another group of providers who provide the same type of services.'' CMS went on to explain that its intent was ''to treat all facilities equally, and apply the same aggregate UPL for each group of facilities, regardless of who owns or operates the facilities.''

133R. Response: Although these commenters assume that this regulation would impose a lower limit on government providers than on private providers, this is not necessarily true. This rule would permit payment of the full cost of Medicaid services to government providers, which could exceed the payments available under limits based on Medicare payment methodologies (for example the Medicare inpatient prospective payment system).

As we discussed in the preamble to the provisions of the regulation, there are different incentives at work in setting Medicaid payment rates to governmentally-operated health care providers that are not relevant for private health care providers. There is the potential for an inherent conflict of interest in setting Medicaid payment rates to governmentally-operated health care providers, arising from the ability of governmental providers to contribute the non-federal share of Medicaid expenditures and from the interrelated nature of governmental units within a State. Limits based on documented costs results in an objective basis to assess whether a rate is consistent with efficiency, economy and quality of care, because it provides for full payment for the costs of furnishing covered services to eligible individuals.

The rational basis for distinguishing between governmentally-operated and private health care providers is shown by the preponderance of States that have separate payment methodologies for governmentally-operated and private health care providers.

In our 2002 issuance, this was not an issue upon which we focused; this regulation reflects additional consideration and analysis obtained through oversight reviews of Medicaid State plans and programs.

134C. Comment: One commenter stated that given the limited definition of ''unit of government'', there are providers who today receive payments in excess of cost. Since CMS does not limit payment to those providers to cost, it should not apply a cost limit to public providers either.

Another commenter provided an example of how States design their reimbursement systems to differentiate payments between an acute care hospital and a psychiatric care facility. The commenter stated that public and private entities in the acute care hospital category would be paid the same rate based on the services they provide and the State would develop a separate rate for a psychiatric care facility and apply it to both the public and private entities. The commenter stated that the proposed cost limit would force States to dismantle this reasonable payment methodology.

134R. Response: The Federal Medicaid statute does not reference ''public'' health care providers for purposes of State Medicaid financing, but only health care providers operated by units of government. The regulation limits governmentally-operated health

care providers to reimbursements that do not exceed the individual provider's cost of serving Medicaid eligible individuals. This regulation does not preclude States from using the same payment methods for governmental and private providers, as long as governmental providers are not paid in excess of cost. To the extent that private providers are paid less than their full cost, this rule would give States flexibility to pay governmental providers at a higher rate than private providers. This rule allows governmentally-operated Medicaid providers to be reimbursed for their full cost of providing services to Medicaid individuals. While the regulation does not impose a Medicaid cost limit on private health care providers, our reviews of Medicaid reimbursement methodologies indicate that some States reimburse private health care providers at rates that are less than the cost of serving Medicaid eligible individuals.

The limit on reimbursement not to exceed cost for individual health care providers operated by units of government is consistent with statutory construction that the Federal government pays only its proportional cost for the delivery of Medicaid services. Because the Medicaid program is jointly funded by Federal, State, and local governments, we do not find it appropriate that units of State or local government would ''profit'' from Federal taxpayer dollars that are intended to match a percentage of the cost of providing services to Medicaid individuals.

In addition, the provisions of the regulation do not force States to dismantle any of the existing Medicaid reimbursement rate methodologies they are currently utilizing to reimburse health care providers. Under the Medicaid cost limit, States may continue to use Medicaid reimbursement rate methodologies, but will need to compare such rates to the actual cost of providing services to Medicaid individuals and make reconciling adjustments in the event of overpayments to a particular governmentally-operated health care provider. States may find such cost reconciliations to be useful inasmuch as they will permit States to better analyze the reasonableness of their Medicaid reimbursement rates.

We considered imposing cost limits on Medicaid payments to governmentally-operated health care providers only when those health care providers were paid differently than private health care providers. This approach, however, would have required considerably more oversight resources and would be subject to abuse. We foresaw that States could evade the intended limits by segmenting generally applicable payment rates in ways that effectively distinguished between governmentally-operated and private health care providers (for example, by developing a generally applicable payment rate that included a special payment for providers operating in a city with a population between 300,000 and 350,000 that has no less than 1350 beds and no more than 1360 beds). This outcome would not be consistent with the overall principle to end excessive payments to governmental providers.

135C. Comment: One commenter stated that since CMS has noted on numerous occasions that States have no incentive to overpay providers if the providers cannot transfer funds back to the State, CMS should consider limiting the application of provider specific cost limits to only those instances in which payment methodologies for government providers differ from the payment methodologies for non-government providers. If payments to government and non-government providers are the same, the expense of cost reporting is not offset by any savings.

135R. Response: We considered imposing cost limits on Medicaid payments to governmentally-operated health care providers only when those health care providers were paid differently than private health care providers. This approach, however, would have required considerably more oversight resources and would be subject to abuse. We foresaw that States could evade the intended limits by segmenting generally applicable payment rates in ways that effectively distinguished between governmentally-operated and private health care providers (for example, by developing a payment rate that included a special payment for health care providers operating in a city with a population between 300,000 and 350,000 that has no less than 1,350 beds and no more than 1,360 beds). This outcome would not be consistent with the overall principle to end excessive payments to governmentally-operated health care providers.

An upper payment limit based on documented cost provides a clear, objective test of the reasonableness of a payment methodology for government providers regardless of whether the provider participates in financing the Medicaid program. The cost limit on Medicaid reimbursement is consistent with the overall Federal, State and local partnership under which the Federal government pays only its proportional cost for the delivery of Medicaid services. It is not appropriate that units of State or local government would ''profit'' from Federal taxpayer dollars that are intended to match a percentage of the cost of providing services to Medicaid individuals.

As important, a separate test for governmental providers that participate in financing the Medicaid program could be viewed as contrary to the statutory protection of such financing arrangements. State governments may share their fiscal obligation to the Medicaid program with local governments according to the instruction of Congress. Under Public Law 102–234, the Congress made clear that States may allow governmentally-operated health care providers to participate in a State's fiscal obligation to the Medicaid program through the use of intergovernmental transfers and certified public expenditures.

Under this regulation, States may continue to pay governmentally-operated and non-governmentally-operated health care providers under the same Medicaid reimbursement rate, as long as the applicable upper payment limits are met for each category of provider. The provisions of the regulation do not require States to dismantle any of the existing Medicaid reimbursement rate methodologies they are currently utilizing to reimburse providers. Under the Medicaid cost limit, States may continue to use existing Medicaid reimbursement rate methodologies, but will need to compare such rates to the actual cost of providing services to Medicaid individuals and make reconciling adjustments in the event of overpayments to a particular governmentally-operated health care provider.

136C. Comment: Several commenters specified how the proposed cost limit and other provisions of the regulation will create difficult financing situations for the hospitals operating within their State. For example, the commenters noted that either a hospital will be considered private and therefore unable to share in the funding of the non-federal share of Medicaid payments or it will be considered governmental and able to fund the non-federal share, but subject to the cost limit. The commenters argued that either way, these facilities will be faced with significant financial losses; even in some States that CMS has indicated employ appropriate IGTs.

136R. Response: This rule restores some measure of fiscal integrity to Medicaid financing and payment for governmental providers. We agree that

governmental providers (or non-governmental providers erroneously treated as such) that were paid in excess of their actual costs of providing Medicaid services may be adversely affected. Section 1901 of the Medicaid statue, however, makes clear that the intended beneficiaries of under the Medicaid statute are eligible individuals, not providers. By providing that Medicaid payments may be sufficient to cover the full cost of covered services at government providers, we are protecting the interest of those eligible individuals. Moreover, by providing that providers are entitled to retain Medicaid payments, we are ensuring that Medicaid payments are, in fact, available to pay for covered services and are not diverted for other purposes.

The Medicaid program is jointly funded by Federal, State, and local governments. We do not find it appropriate that units of State or local government would ''profit'' from Federal taxpayer dollars that are intended to match a percentage of the cost of providing services to Medicaid individuals. As we have examined Medicaid financing arrangements across the country, we have found that many States make payments to governmentally operated providers that are in excess of cost. These providers, in turn, use the excess of Medicaid revenue over cost to subsidize health care operations that are unrelated to Medicaid, or they may return a portion of such payments to the State as a source of revenue. In either case, we do not find that Medicaid payments in excess of cost to governmentally-operated health care providers are consistent with the statutory principles of economy and efficiency as required by section 1902(a)(30)(A) of the Act, nor do we find such excessive payments to be consistent with the statutory structure requiring that the Federal government match a percentage of State or local government expenditures for the provision of services to Medicaid individuals.

Non-governmentally-operated health care providers, including many of the ''public'' safety net hospitals, are *not* affected by the cost limit provision of the regulation and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements. Moreover, one provision of the regulation reaffirms State Medicaid financing policy requiring that health care providers be allowed to fully retain their Medicaid payments, another provision of which clearly demonstrates the Federal government's intent to protect the nation's public safety net and its ability to continue delivering critical health care services to Medicaid individuals and the uninsured. Any health care providers that become ineligible to participate in the State financing of Medicaid payments following the effective date of the provisions of this regulation can realize greater net revenues if State or local government funding sources are utilized to fund non-Federal share obligations to Medicaid payments historically financed by non-governmentally-operated ''public'' health care providers.

137C. Comment: One commenter requested clarification of whether States that do not use CPEs to pay providers are required to review annual cost reports to verify that actual payments to each governmentally operated provider did not exceed the provider's costs. The commenter questioned whether this provision applies to Medicaid payments that are not developed using IGTs or CPEs.

137R. Response: Yes, the provisions of the regulation require States to review cost reports on an annual basis for all governmentally-operated health care providers to verify compliance with the Medicaid cost limit, even if the governmentally-operated health care provider was not involved in IGTs or CPEs.

138C. Comment: A few commenters indicated that while proposed § 447.206 requires the use of the applicable Medicare cost report to document the costs incurred by hospitals and nursing homes operated by units of government, many States have developed their own State specific cost reports. These commenters have found the Medicare cost report did not provide the detailed information needed for rate setting processes and that the State specific cost report provided much more detailed information by cost center. These commenters recommend that the proposed rule be modified to allow States to use their own cost report form if the form meets or exceeds the amount of information included in the Medicare cost report. Other commenters recommended that the final rule also be clarified to allow State cost reports to be used as the basis for the cost settlement of government providers in lieu of the Medicare cost report. In addition, the commenter recommended that State cost principles may be used in the settlement determination. Another commenter stated that is not clear that there is a consistent use, review or audit of the Medicare cost reports and that there is an increasing probability for these cost reports to contain errors and/or omissions. This commenter recommended that CMS allow for other means to document provider costs in the event alternative sources prove more accurate and reliable.

138R. Response: The Medicare cost allocation process utilized for institutional health care providers is considered a key component in determining Medicaid cost under the provisions of the regulation. Use of a nationally recognized, standardized cost report allows all States to document institutional Medicaid service costs in a nationally consistent manner. Institutional governmentally-operated health care providers (that is, hospitals (encompassing both inpatient and outpatient hospital services), nursing facilities, and intermediate care facilities for the mentally retarded (ICFs/MR)) will be required to provide the State with data extracted from primary source documents as well as copies of the source documents. These documents would include the governmentally-operated health care provider's Medicare cost report (or Medicaid cost report for intermediate nursing facility care and ICFs/MR consistent with Medicare cost reporting principles), and audited financial statements that will be used in conjunction with information provided by the States' Medicaid Management Information Systems (MMIS).

States will not be required to audit financial and cost information provided by individual institutional governmentally-operated health care providers as part of the Medicaid cost limit review. Each of the source documents is subject to reporting and auditing rules specific to the original purpose of that document and independent of the Medicaid cost limit and State review process. The State must render an determination on the cost limit methodology applied to the source documents but will not be required to validate the accuracy of the information and data within the source documents.

For non-institutional services provided to Medicaid eligible individuals, a nationally recognized, standard cost report does not exist. Because of this, we intend to publish a standardized cost reporting form to document the costs of such services. The purpose of this standardized form is to document in a uniform manner the cost of providing non-institutional services to Medicaid individuals. The period of time to which this cost report applies will be the Medicaid State plan rate year.

CMS has developed a general Medicaid Cost Reporting Protocol that

will be available on the CMS Web site that specifically addresses the information utilized from each source document and the methods under which institutional (and non-institutional) Medicaid costs will be determined. The protocol was designed to provide States with detailed instructions to determine compliance with the Federal requirements.

139C. Comment: Several commenters questioned when the cost report form for non-hospital and non-nursing facility services that is mentioned, would be available. One commenter inquired as to whether the Secretary will prospectively provide the form or will States have to develop the form and hope that their form meets the Secretary's retrospective approval. These commenters also questioned what happens in cases where rates have been established and approved by CMS, but do not potentially meet the cost test provided by the form. These commenters are particularly concerned since many of these providers (i.e., school-based service providers, health department clinics, community mental health clinics, physician services provided by State employees) have never been required to produce cost report information.

Another commenter was concerned about the impact on home and community based waiver programs and the imposition of these requirements threatens to undermine the viability of these very important programs. The commenters stated that it is difficult to gauge the impact since cost data for non-institutional services has never been captured. But regardless, this will encompass many providers and will require great effort by States and providers to collect, report, analyze and reconcile these costs annually. Other commenters noted that many of these non-institutional providers are generally paid on a fee-based system, which is relatively inexpensive and easy to administer. These commenters believe that imposing cost reporting requirements on these providers will be difficult and in many cases impossible for them to manage. They further believe that these providers may then find it no longer worthwhile to continue providing Medicaid services.

139R. Response: We do not believe the Medicaid cost limit will impose significant administrative burden on States particularly since such limit applies only to governmentally-operated health care providers. Moreover, the benefit of clear and transparent accounting for the costs of medical assistance furnished by governmental providers will be significant. Accurate data on Medicaid costs will be available to guide Medicaid payment determinations by the State.

For non-institutional services provided to Medicaid eligible individuals, a nationally recognized, standard cost report does not currently exist. Because of this, we intend to publish a standardized cost reporting form to document the costs of such services. The purpose of this standardized form is to document in a uniform manner the cost of providing non-institutional services to Medicaid individuals. The period of time to which this cost report applies will be the Medicaid State plan rate year.

140C. Comment: One commenter indicated that the requirement that providers of non-institutional/non-acute care Medicaid services operated by units of government must submit annual cost reports to ensure Medicaid reimbursements do not exceed the allowable Medicaid costs of the provider, is in direct conflict with the current direction provided by CMS' Non-Institutional Payment Team (NIPT). The commenter stated that the NIPT has advised that if Medicaid rates are established using Medicare or commercial rates as the basis, cost reports would no longer be required from these providers unless certified public expenditures are used. This commenter recommends the use of market-based rates. By moving to market-based rates, States have the same incentive as private providers to control their costs to stay within the market based rates and that by allowing providers to be reimbursed up to cost, it is usually interpreted by providers as an entitlement for these providers to be able to recover their full cost. There is no incentive to control costs. With guidance from the NIPT, the commenter was advised to eliminate the cost report requirement as an incentive for State agencies to voluntarily move to market-based rates. The commenter urges CMS to modify the proposed rule to remove the requirement for cost reports for non-institutional services when a CMS-approved market based reimbursement methodology is used and the services are not funded through a CPE.

Another commenter stated that Medicare rates used by States as payments for their Medicaid programs should be exempt from the cost settlement process. This commenter explained that if this proposed cost limit extends to programs that currently do not have a cost report, but some of these programs may use Medicare rates, the State may need to develop a new cost report that applies only to government providers solely to determine their cost for cost settlement.

140R. Response: There are no Medicaid reimbursement rate methodologies for governmentally-operated health care providers that would be ''exempt'' from the Medicaid cost limit provision of this regulation. The regulation does not require States to modify any of the existing Medicaid reimbursement rate methodologies they are currently utilizing to reimburse governmentally-operated health care providers. Under the Medicaid cost limit, States will be able to continue to use existing reimbursement rate methodologies, but will need to compare such rates to the actual cost of providing services to Medicaid individuals and make reconciling adjustments in the event of overpayments to a particular governmentally-operated health care provider. Prior agency guidance is superseded by this regulation.

For non-institutional services provided to Medicaid eligible individuals, a nationally recognized, standard cost report does not exist. Because of this, we intend to publish a standardized cost reporting form to document such services. The purpose of this standardized form is to document in a uniform manner the cost of providing non-institutional services to Medicaid individuals. The period of time to which this cost report applies will be the Medicaid State plan rate year.

CMS has modified the regulation to include a transition period to allow States and governmentally operated non-institutional health care providers sufficient time to develop and implement Medicaid cost documentation and reporting processes consistent with the cost report template issued by CMS (including but not limited to changes in State/provider reporting systems, changes to the Medicaid State plan, changes to time studies, establish periodic review and audit processes, etc.). States will not be required to document and report cost information associated with non-institutional Medicaid services until the State's Medicaid State plan rate year 2009. Actual submission of the State's summary report on the Medicaid cost limit for non-institutional services will not be due to CMS until December 31, 2011, which allows States an opportunity to implement periodic review and audit processes for Medicaid non-institutional costs starting in Medicaid State plan rate year 2009.

CMS has developed a general Medicaid Cost Reporting Protocol that will be available on the CMS website

that specifically addresses the methods under which non-institutional (and institutional) Medicaid costs will be determined. The protocol was designed to provide States with detailed instructions to determine compliance with the Federal requirements.

141C. Comment: One commenter stated that they identified several providers which may be governmental providing other than hospital or nursing services in the less populated areas of the State. The commenter suggested that CMS should acknowledge the true impact on smaller units of government or governmentally-operated health care providers and provide some floor criteria below which the regulations would not apply. The commenter offered some examples of potential floor criteria: The number of facility beds; Medicaid eligible population in some mile radius; number of Medicaid individuals served by the unit of government or governmental health provider and population base in the unit of government's area. Another commenter suggested other bases for exemption: The extent to which public providers are a significant percentage of the total providers using the same reimbursement methodology; a dollar reimbursement threshold; or a demonstration that reimbursement in the aggregate does not exceed cost.

141R. Response: Although we note the unique circumstances of providers in less populated areas, the provisions of the regulation are intended to apply uniformly across the country, regardless of a provider's particular size, location, or reimbursement characteristics unique to certain governmentally-operated health care providers.

It is important to note that ''public'' providers are not subject to the Medicaid cost limit. Only governmentally-operated health care providers will be subject to the Medicaid cost limit. Non-governmentally-operated health care providers, including many of the ''public'' safety net health care providers, are *not* affected by the cost limit provision of the regulation and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements.

142C. Comment: One commenter was concerned about the impact of Medicare cost reports on physician services. The commenter stated that Medicare separates out the professional services component that is covered under Part B, leaving only the cost of physician services to the hospital on the hospital cost report. In this circumstance, there is no similar rationale under Medicaid for public hospitals since they directly employ or contract for physicians to serve their patients. Other commenters recommended that physician services be excluded from the cost limit.

142R. Response: The Federal Medicaid statute does not include a term nor discussion that references a ''public'' health care provider for purposes of State Medicaid financing. The regulation limits governmentally-operated health care providers to reimbursements that do not exceed the individual provider's cost of serving Medicaid eligible individuals. Governmentally-operated entities that are paid by the State as providers of physician services are subject to the Medicaid cost limit. Costs to governmentally-operated entities paid by the State as providers of physician services rendered outside the hospital will be documented using the standardized cost reporting form issued by CMS that will be used to document such services. The purpose of this standardized form is to document in a uniform manner the cost of providing non-institutional services to Medicaid individuals.

The Medicaid Cost Reporting Protocol that will be available on the CMS Web site addresses the methods under which institutional and non-institutional Medicaid costs will be determined. The protocol was designed to provide States with detailed instructions to determine compliance with the Federal requirements.

143C. Comment: One commenter requested clarification regarding discrepancies between the preamble and proposed regulatory text at § 447.206. The commenter stated that the preamble suggests the use of Medicare cost reports for hospitals and nursing facility services with exceptions to be addressed on a case-by-case basis, but the regulation text states that costs for such services ''must'' be supported using Medicare cost report information.

143R. Response: The Medicare cost allocation process utilized for institutional health care providers is considered a key component in determining Medicaid cost under the regulation. Institutional governmentally-operated health care providers (i.e. hospitals (encompassing both inpatient and outpatient hospital services), nursing facilities, and intermediate care facilities for the mentally retarded (ICFs/MR)) will be required to provide the State with data extracted from primary source documents as well as copies of the source documents. These documents would include the governmentally-operated health care provider's Medicare cost report (or Medicaid cost report for intermediate nursing facility care and ICFs/MR consistent with Medicare cost reporting principles), and audited financial statements that will be used in conjunction with information provided by the States' Medicaid Management Information Systems (MMIS).

For purposes of institutional governmentally-operated health care providers, the Medicaid cost limit determination will rely on existing reporting tools used by institutional health care providers. States will not be required to audit financial and cost information provided by individual institutional governmentally-operated health care providers as part of the Medicaid cost limit review. Each of the source documents is subject to reporting and auditing rules specific to the original purpose of that document and independent of the Medicaid cost limit and State review process. The State must render an determination on the cost limit methodology applied to the source documents but will not be required to validate the accuracy of the information and data within the source documents.

144C. Comment: One commenter requested that CMS specify in the regulation text the process, timeframes, and appeal rights regarding CMS' action on a State's request to approve its cost reports for non-hospital/non-nursing facility providers, and for adjusted Medicare cost reports for hospitals/nursing facilities.

144R. Response: States will not be expected to develop their own cost reports for purposes of the Medicaid cost limit under the regulation. For non-institutional services provided to Medicaid eligible individuals, a nationally recognized, standard cost report does not currently exist. Because of this, we intend to publish a standardized cost reporting form to document the costs of such services. The purpose of this standardized form is to document in a uniform manner the cost of providing non-institutional services to Medicaid individuals. The period of time to which this cost report applies will be the Medicaid State plan rate year.

CMS has modified the regulation to include a transition period to allow States and governmentally-operated non-institutional health care providers sufficient time to develop and implement Medicaid cost documentation and reporting processes consistent with the cost report template issued by CMS (including but not limited to changes in State/provider reporting systems, changes to the

Medicaid State plan, changes to time studies, establish periodic review and audit processes, etc.), States will not be required to document and report cost information associated with non-institutional Medicaid services until the State's Medicaid State plan rate year 2009. Actual submission of the State's summary report on the Medicaid cost limit for non-institutional services will not be due to CMS until December 31, 2011, which allows States an opportunity to implement periodic review and audit processes for Medicaid non-institutional costs starting in Medicaid State plan rate year 2009.

CMS has developed a general Medicaid Cost Reporting Protocol that will be on the CMS website that specifically addresses the methods under which non-institutional (and institutional) Medicaid costs will be determined. The protocol was designed to provide States with detailed instructions to determine compliance with the Federal requirements.

145C. Comment: Many commenters were confused by the proposed language in §§ 447.206(d) through 447.206(e). The commenters stated that CMS alternated between mandatory and permissive language regarding the State obligations during CPE reconciliations. The commenters believed that CMS' intent was to require the submission of cost reports whenever providers are paid using a cost reimbursement methodology funded by CPEs and to permissively allow States to provide interim payment rates based on the most recently filed prior year cost reports. They also believed States providing interim payment rates must undertake an interim reconciliation based on filed cost reports for the payment year in question and a final reconciliation based on finalized cost reports. The commenters also believed CMS' intent was that for providers whose payments are not funded by CPEs, the providers are required to submit cost reports and the State is required to review the cost reports and verify that payments during the year did not exceed costs. The commenters requested CMS confirm this understanding of the regulatory language.

145R. Response: Under the Medicaid cost limit provision of the regulation, States may continue to use existing Medicaid reimbursement rate methodologies, which are not funded by CPEs, but will need to compare such rates to the actual cost of providing services to Medicaid individuals and make reconciling adjustments in the event of overpayments to a governmentally-operated provider. The Medicaid cost limit provision does not require Medicaid payments to be equal to a governmentally-operated health care provider's cost. The Medicaid cost limit provision instead stipulates that Medicaid payments must be no more than a governmentally-operated health care provider's cost of providing services to Medicaid individuals. Section 447.206(e) specifically addresses situations where governmentally-operated health care providers are reimbursed using Medicaid reimbursement rate methodologies not funded by CPEs.

States must utilize cost reimbursement methodologies for Medicaid payments that are funded by CPEs. Section 447.206(d)(2) indicates that States may utilize interim rates and may trend those interim rates by an applicable health care-related index. If interim rates are used, then interim reconciliations must be performed by reconciling the interim Medicaid payment rates to the ''as filed'' cost report for the spending year in which interim Medicaid payment rates were made. Paragraph (3) of this provision also establishes that final reconciliation must be performed annually by reconciling any Medicaid interim payments to the finalized cost report for the spending year in which all interim payments were made. As stated previously, these procedures related to interim and final reconciliations at § 447.206(d) are applicable when States utilize cost reimbursement methodologies that are funded by CPEs.

146C. Comment: A few commenters requested clarification regarding proposed § 447.206(d)(2). The commenters requested clarification that this section is applicable only in a retrospective cost reimbursement methodology and does not apply to a prospective cost reimbursement methodology. The commenters are concerned that health care providers could construe that States are required to pay full costs, rather than that payments are limited to cost, in a prospective cost reimbursement methodology. Where payments are less than cost, health care providers would argue an additional Medicaid payment would be due.

146R. Response: Under the Medicaid cost limit provision of the regulation, States may continue to use existing Medicaid reimbursement rate methodologies, which are not funded by CPEs, but will need to compare such rates to the actual cost of providing services to Medicaid individuals and make reconciling adjustments in the event of overpayments to a governmentally-operated provider. The Medicaid cost limit provision does not require Medicaid payments to be equal to a governmentally-operated health care provider's cost. The Medicaid cost limit provision instead stipulates that Medicaid payments must be no more than a governmentally-operated health care provider's cost of providing services to Medicaid individuals. Section 447.206(e) specifically addresses situations where governmentally-operated health care providers are reimbursed using Medicaid reimbursement rate methodologies not funded by CPEs.

States must utilize cost reimbursement methodologies for Medicaid payments that are funded by CPEs. Section 447.206(d)(2) indicates that States may utilize interim rates and may trend those interim rates by an applicable health care-related index. If interim rates are used, then interim reconciliations must be performed by reconciling the interim Medicaid payment rates to the ''as filed'' cost report for the spending year in which interim Medicaid payment rates were made. Paragraph (3) of this provision also establishes that final reconciliation must be performed annually by reconciling any Medicaid interim payments to the finalized cost report for the spending year in which all interim payments were made. As stated previously, these procedures related to interim and final reconciliations at § 447.206(d) are applicable when States utilize cost reimbursement methodologies that are funded by CPEs.

147C. Comment: A few commenters requested clarification regarding proposed § 447.206(d)(3). The commenters request clarification that the finalized cost report may be prepared by the Medicaid agency rather than requiring the Medicaid agency to wait for a Medicare intermediary to finalize the cost report. The Medicaid agency shouldn't have to wait for the Intermediary's generated final or accept the Medicare intermediary's determination of Medicaid costs.

147R. Response: The Medicare cost allocation process utilized for institutional health care providers is considered a key component in determining Medicaid cost under the provisions of the regulation. Use of a nationally recognized, standardized cost report allows all States to document institutional Medicaid service costs in a nationally consistent manner. Institutional governmentally-operated health care providers (that is, hospitals (encompassing both inpatient and outpatient hospital services), nursing facilities, and intermediate care facilities for the mentally retarded (ICFs/MR)) will be required to provide

the State with data extracted from primary source documents as well as copies of the source documents. These documents would include the governmentally-operated health care provider's Medicare cost report (or Medicaid cost report for intermediate nursing facility care and ICFs/MR consistent with Medicare cost reporting principles), and audited financial statements that will be used in conjunction with information provided by the States' Medicaid Management Information Systems (MMIS).

States will not be required to audit financial and cost information provided by individual institutional governmentally-operated health care providers as part of the Medicaid cost limit review. Each of the source documents is subject to reporting and auditing rules specific to the original purpose of that document and independent of the Medicaid cost limit and State review process. The State must render an determination on the cost limit methodology applied to the source documents but will not be required to validate the accuracy of the information and data within the source documents.

We understand that there may be delays with the Medicare fiscal intermediary finalizing the Medicare cost report. To ensure compliance with the Medicaid cost limit, we have modified the final regulation to provide a generous but definite timeframe for a State's review of Medicaid payments made to institutional governmentally-operated health care providers. For any cost reports that are not finalized in that timeframe, the State should use the ''as filed'' report and indicate such in the summary report to CMS. The State should then submit a corrected summary report to CMS within 30 days of the finalization of the Medicare cost report.

148C. Comment: A couple of commenters recommended that States be allowed the option of having a single settlement and forgo the interim settlement process when using CPEs. The commenters stated that currently only final settlements are conducted and this interim settlement would require an additional step.

148R. Response: Provisions at § 447.206(d)(2) address reconciliations of interim rates to ''filed'' cost reports, while provisions § 447.206(d)(3) address reconciliations of interim rates to ''finalized'' cost reports. Such a distinction is historically relevant to institutional health care providers (hospitals and nursing homes) which ''file'' cost reports with a Medicare fiscal intermediary, after which the cost report is ''finalized'' following fiscal intermediary review. The provisions at §§ 447.206(d)(2) and 447.206(d)(3) require that reconciliations be performed at both steps for purposes of documenting costs for the institutional health care provider's services to Medicaid individuals.

Non-institutional governmentally-operated health care providers must use the standardized cost reporting form issued by CMS, which will be subject to a State established review and audit process that must also include interim and final reconciliations for purposes of CPE.

149C. Comment: Several commenters requested that the proposed requirement to limit payments to health care providers not funded by CPEs be eliminated.

149R. Response: The Medicaid cost limit provision applies to all health care providers operated by units of government within the State, regardless of how the non-Federal share of Medicaid payments made to the governmentally-operated health care provider are funded.

150C. Comment: One commenter requested clarification in the regulation text on the timing requirements for reconciliation and for final payments.

150R. Response: To ensure compliance with the Medicaid cost limit, CMS has modified the regulation to indicate that a State's review of Medicaid payments made to institutional governmentally-operated health care providers during Medicaid State plan rate year 2008 must be completed no later than the last day of federal fiscal year 2010. The State must submit a summary report of the findings of this review by the last day of calendar year of 2010. The basis for these deadlines is the recognition that hospitals (for both inpatient and outpatient hospital services), nursing homes and ICFs/MR may have a cost reporting period that remains open after the Medicaid State Plan rate year under review has ended. The State review and reporting deadlines allow sufficient time for the cost report period that remains open at the end of a Medicaid State Plan rate year to close and for the cost report to be submitted to the fiscal intermediary. For any cost reports that are not finalized, the State should use the ''as filed'' report and indicate such in the summary report to CMS. The State should then submit a corrected summary report to CMS within 30 days of the finalization of the cost report.

CMS has modified the regulation to include a transition period to allow States and governmentally-operated non-institutional health care providers sufficient time to develop and implement Medicaid cost documentation and reporting processes consistent with the cost report template issued by CMS (including but not limited to changes in State/provider reporting systems, changes to the Medicaid State plan, changes to time studies, establish periodic review and audit processes, etc.), States will not be required to document and report cost information associated with non-institutional Medicaid services until the State's Medicaid State plan rate year 2009. Actual submission of the State's summary report on the Medicaid cost limit for non-institutional services will not be due to CMS until December 31, 2011, which allows States an opportunity to implement periodic review and audit processes for Medicaid non-institutional costs starting in Medicaid State plan rate year 2009.

151C. Comment: Many commenters stated that the proposed cost limit would impose deep cuts in safety net support without addressing the inappropriate Medicaid financing abuses CMS has been working to address. The commenters acknowledged that according to CMS it has eliminated ''recycling'' the cost limit is supposed to address. Yet the commenters argued that imposing the proposed cost limit will do nothing to address recycling, rather it will only result in limiting net funding to governmental providers. The commenters recommended that rather than imposing the new cost limit, CMS should continue to address issues on a case-by-case basis through State Plan amendment (SPA) review.

Several commenters disagreed with CMS' statements in the proposed rule that States operate inappropriate financing structures. The commenters stipulated the States have worked to ensure that their financing policies do not denigrate the integrity of the Medicaid program and have received approval by CMS for these systems. Further, States have been subject to significant State and federal audit reviews and the commenters argued that these audit reviews and oversight mechanisms are sufficient for identifying any future potential threats to the integrity of the Medicaid program rather than the burdensome provisions within this proposed rule.

Similarly, one commenter discussed their example of working with CMS to approve a nursing facility reimbursement methodology that authorized payments to county-operated nursing facilities at 94 percent of the Medicare payment rate with the understanding that the counties would be contributing, through IGTs, to the

State a portion of the payment in an amount not to exceed the non-federal share. The commenter stated that through the review of this SPA all of the issues raised by CMS were addressed. The commenter believed that this is a prime example of the federal-State partnership at work. The commenter noted that the ability of CMS to deal through the State plan process with what it perceived to be a financing problem and to work with the State to develop a solution demonstrates why there is no need for further regulation. Several other commenters noted that after working extensively with CMS by removing problematic IGTs, they are now characterized as using IGTs appropriately.

151R. Response: We understand that many States utilize Medicaid financing methods that are consistent with the Medicaid statute and that existing Federal oversight mechanisms have been effective in addressing a number of State Medicaid financing abuses. An upper payment limit based on documented cost is nevertheless justified to prevent excessive payments to governmental providers. Such an upper payment provides a clear, objective test of the reasonableness of a payment methodology for government providers regardless of whether the provider participates in financing the Medicaid program. This limit is also consistent with statutory construction that the Federal government pays only its proportional cost for the delivery of Medicaid services. Because the Medicaid program is jointly funded by Federal, State, and local governments, we do not find it appropriate that units of State or local government would ''profit'' from Federal taxpayer dollars that are intended to match a percentage of the cost of providing services to Medicaid individuals.

Under the provisions of the regulation, governmentally-operated health care providers will be permitted to receive up to 100 percent of the cost of serving Medicaid individuals. It does not appear that limiting Medicaid reimbursement to full cost would hurt a governmentally-operated health care provider, unless the governmentally-operated health care provider had been historically receiving Medicaid payments above cost and using excess Medicaid revenues to subsidize costs outside of the Medicaid program. In such a situation, the Medicaid cost limit could cause a net reduction in Medicaid revenue to the governmentally-operated health care provider, but the amount of the reduction would directly correspond with the amount of Medicaid revenues that had been used to satisfy non-Medicaid activities.

152C. Comment: Many commenters were concerned that the proposed cost limit would not allow health care providers to include important elements in their cost calculation. One commenter questioned whether the Secretary would prospectively establish the reasonable methods to identify and allocate Medicaid costs. For example, several commenters cited costs for physician services, on-call availability costs, capital costs and health information technology costs. These commenters recommended that CMS allow the reasonable costs necessary for the continued operation of health care providers. Other commenters recommended that CMS provide guidance on how Medicaid costs would be determined and that at a minimum any determination of Medicaid costs would include all costs necessary to operate a governmental facility. These commenters cited many examples.

A few commenters inquired as to what cost finding principles will be used to determine which costs are associated with the provision of the Medicaid service. One commenter further questioned whether the cost finding principles would be standardized, how will they differ from existing cost finding guidance and, why. This commenter stipulated that a more comprehensive definition of costs is needed since CMS has decided not to use Medicare's cost principles or the principles of OMB Circular A–87.

The commenters also noted that some costs on a hospital's cost report are allocated to cost centers judged to be unreimbursable for purposes of Medicare, but are appropriately reimbursed under Medicaid or DSH. Such costs include costs for a clinic that exclusively serves Medicaid and uninsured individuals.

152R. Response: Medicaid service costs must be documented for institutional providers through Medicare cost reporting methods. We agree some adjustments would be needed to reflect the costs of Medicaid services; for example, Medicaid only units that would be excluded from the calculation of Medicare patient care costs would be included in calculating Medicaid patient care costs (and non-Medicaid units would be excluded). But all the information necessary to calculate Medicaid cost should be found on the Medicare cost report. For non-institutional services provided to Medicaid eligible individuals, a nationally recognized, standard cost report does not currently exist. Because of this, we intend to publish a standardized cost reporting form to document the costs of such services.

The Medicare cost allocation process utilized for institutional health care providers is considered a key component in determining Medicaid cost under the regulation. Institutional governmentally-operated health care providers (that is, hospitals (encompassing both inpatient and outpatient hospital services), nursing facilities, and intermediate care facilities for the mentally retarded (ICFs/MR)) will be required to provide the State with data extracted from primary source documents as well as copies of the source documents. These documents would include the governmentally-operated health care provider's Medicare cost report (or Medicaid cost report for intermediate nursing facility care and ICFs/MR consistent with Medicare cost reporting principles), and audited financial statements that will be used in conjunction with information provided by the States' Medicaid Management Information Systems (MMIS).

For non-institutional services provided to Medicaid eligible individuals, use of a standardized form will document in a uniform manner the cost of providing non-institutional services to Medicaid individuals. The period of time to which this cost report applies will be the Medicaid State plan rate year.

CMS has developed a general Medicaid Cost Reporting Protocol that will be available on the CMS website that specifically addresses the information utilized from each source document and the methods under which institutional and non-institutional Medicaid costs will be determined. The protocol was designed to provide States with detailed instructions to determine compliance with the Federal requirements.

153C. Comment: One commenter questioned whether CMS would define which provider costs and what specific Medicare/Medicaid 2552–96 worksheets and lines may be included in developing this new cost limit.

153R. Response: CMS has developed a general Medicaid Cost Reporting Protocol that will be on the CMS Web site that specifically addresses the information utilized from each source document, including the Medicare 2552–96 hospital cost report, and the methods under which institutional and non-institutional Medicaid costs will be determined. The protocol was designed to provide States with detailed instructions to determine compliance with the Federal requirements.

154C. Comment: One commenter questioned whether CMS intends to develop case mix indices for non-institutional providers or require States to do so.

154R. Response: States utilizing Medicaid cost reimbursement methodologies may develop interim payment rates based on prior period costs or case-mix and apply a related health inflation index. However, the Medicaid cost limit provision limits Medicaid payments to the actual costs of providing services to Medicaid individuals and the State must reconcile these interim payments to actual documented cost.

155C. Comment: One commenter was concerned that costs for preventive and wellness care services would not be allowable. The commenter is also concerned that costs for physical therapists would not be allowed. The commenter states the importance of these services in helping individuals maintain their health by preventing further deterioration or future illness.

155R. Response: CMS will continue to provide Federal matching funds for State expenditures under the authority of a State's approved Medicaid State plan. Provided that preventive and wellness services and physical therapy services for Medicaid individuals are considered reimbursable costs under the approved State Plan, CMS will continue to provide Federal funds to match State expenditures for these services to the extent all such reimbursements and State financing are consistent with Federal requirements.

156C. Comment: Many commenters requested that CMS confirm that graduate medical education (GME) costs would be considered allowable costs as part of the proposed cost limit. These commenters cited that as of 2005, 47 States and the District of Columbia provided explicit GME payments to teaching hospitals and that numerous approved State plan provisions authorize such payments. These commenters stated that excluding these costs could seriously undermine the infrastructure for training new physicians across the country.

156R. Response: The allowability of graduate medical education (GME) costs or payment is not affected by this regulation. This issue is the subject of a recently issued Notice of Proposed Rulemaking, which would make unallowable payment for direct GME costs, consistent with the concept included in the President's Budget for Fiscal Year 2008.

157C. Comment: One commenter requested clarification regarding how States should identify costs for providers operated by units of government that do not serve Medicare individuals and, therefore, do not use and have never used Medicare cost reports.

157R. Response: Nursing homes that only provide intermediate care services and therefore do not file a Medicare cost report must use State cost reports generally consistent with the Medicare cost reporting principles utilized in the Medicare 2540 cost report form to determine costs associated with skilled care services.

While Medicare does not have an equivalent cost report for the services provided in ICFs/MR, we recognize that States typically follow Medicare cost principles in determining Medicaid payment rates for ICFs/MR. We further note that the services provided in ICFs/MR are predominately delivered to Medicaid eligible individuals. Therefore, cost data should be extracted from existing State cost reports for services provided in ICFs/MR. Such cost reports must be generally consistent with Medicare cost reporting principles.

For non-institutional services provided to Medicaid eligible individuals, a nationally recognized, standard cost report does not currently exist. Because of this, we are publishing a standardized cost reporting form to document the costs of such services. The purpose of this standardized form is to document in a uniform manner the cost of providing non-institutional services to Medicaid individuals. The period of time to which this cost report applies will be the Medicaid State plan rate year.

158C. Comment: One commenter indicated that there are a broad array of indirect and unreimbursed costs associated with Medicaid individuals. The commenter argued that the uniqueness of Medicaid individuals' socio-economic status make them much costlier. For example, the commenter detailed that Medicaid individuals have a higher rate of missed appointments than private pay or Medicare individuals, under utilize preventive care which then leads to more costly and complex care, increased severity of medical conditions, lack of follow-through or compliance with treatment plans, and use of hospital emergency rooms as a primary care source. The commenter urged CMS to ensure that the true costs associated with Medicaid individuals are captured and the cost limit not be based on strictly patient care costs. Another commenter indicated that limiting reimbursement to costs only would be devastating to facilities operating in States that do not adjust each year for the real costs to provide services to the frail and elderly.

158R. Response: The cost reporting mechanisms that would be used have sufficient flexibility to ensure determination of the full cost of furnishing Medicaid services. At the same time, they will provide a standardized and uniform cost determination methodology.

The Medicare cost allocation process utilized for institutional health care providers is considered a key component in determining Medicaid cost under the regulation. Institutional governmentally-operated health care providers (that is, hospitals, nursing facilities, and intermediate care facilities for the mentally retarded (ICFs/MR)) will be required to provide the State with data extracted from primary source documents as well as copies of the source documents. These documents would include the governmentally-operated health care provider's Medicare cost report (or Medicaid cost report for intermediate nursing facility care and ICFs/MR consistent with Medicare cost reporting principles), and audited financial statements that will be used in conjunction with information provided by the States' Medicaid Management Information Systems (MMIS).

For non-institutional services provided to Medicaid eligible individuals, a nationally recognized, standard cost report does not currently exist. Because of this, we are publishing a standardized cost reporting form to document the costs of such services. The purpose of this standardized form is to document in a uniform manner the cost of providing non-institutional services to Medicaid individuals. The period of time to which this cost report applies will be the Medicaid State plan rate year.

159C. Comment: One commenter stated that since their rates for Medicaid services have not been indexed for inflation over the past fourteen years, it shouldn't be necessary for them to prove costs.

159R. Response: There are no Medicaid reimbursement rate methodologies for governmentally-operated health care providers that would be ''exempt'' from the Medicaid cost limit provision of the regulation. The regulation does not require States to modify existing Medicaid reimbursement rate methodologies they are currently utilizing to reimburse governmentally-operated health care providers. Under the Medicaid cost limit, States will be able to continue to use existing reimbursement rate methodologies, but will need to

compare such rates to the actual cost of providing services to Medicaid individuals and make reconciling adjustments in the event of overpayments to a particular governmentally-operated health care provider.

160C. Comment: One commenter suggested that CMS give consideration to those States that have approved cost based prospective reimbursement plans. The commenter added that by doing this, the proposed cost limit requirement could be met with the most recent historical costs used in establishing the prospective rates.

160R. Response: The Medicaid cost limit provision of the regulation requires an examination of the actual costs incurred by governmentally-operated health care providers for providing services to Medicaid individuals and the actual Medicaid payments received for such services in a given Medicaid State plan rate year. Under the Medicaid cost limit, States will be able to continue to use existing reimbursement rate methodologies, but will need to compare such rates to the actual cost of providing services to Medicaid individuals and make reconciling adjustments in the event of overpayments to a particular governmentally-operated health care provider.

161C. Comment: Several commenters stated that they have no issue with the requirement to submit auditable documentation, but are concerned whether CMS considered that complicated approved methodologies exist today whereby both administrative and program costs, through cost allocation, are used to claim administrative costs by CPEs and are used to set rates for programs such as TCM. The commenters asked CMS to understand that while the requirements for reporting administrative costs and for reporting service costs are very different, they are also sometimes integrated in time studies.

The commenters preferred that documentation requirements accommodate both administrative claiming and/or collection of the cost to provide a service, avoiding a duplicative reporting process.

161R. Response: The standardized cost reporting form will be used to document non-institutional services has been designed to accommodate both administrative Medicaid costs as well as clinical Medicaid costs in a single template, thus avoiding a duplicative reporting process. CMS has developed a general Medicaid Cost Reporting Protocol that will be on the CMS Web site that specifically addresses the methods under which non-institutional (and institutional) Medicaid costs will be determined. The protocol was designed to provide States with detailed instructions to determine compliance with the Federal requirements. While the Medicaid cost limit provision does not necessarily require States to modify their existing Medicaid reimbursement rate methodologies for governmentally-operated health care providers, any Medicaid overpayments that result from such reimbursement methodologies, must be offset against future claimed expenditures reported on the CMS–64 as an overpayment in accordance with sections 1903(d)(2) and 1903(d)(3)(A) of the Act.

162C. Comment: Several commenters inquired as to what extent CMS will define how administrative claiming is documented and how would these proposed regulations might alter that process. The commenters request that these requirements not go beyond activities defined in OMB A–87 or GAAP. The commenters also expect that the allowable costs be fully inclusive of costs as defined by OMB A–87. Another commenter questioned whether the proposed cost limit will be applied to Medicaid administrative costs. Another commenter questioned if the cost identification and reporting requirements apply to administrative expenditures, will all currently approved Cost Allocation Plans still be compliant under this proposed rule.

162R. Response: OMB Circular A–87 specifies cost principles for state and local government administration costs. Cost Allocation Plans are required and approved by the Federal government in accordance with 45 CFR Part 95, Subpart E. Cost identification and reporting requirements will continue under this existing process for purposes of administrative expenditures under Medicaid.

163C. Comment: A few commenters expressed concern regarding the impact of the proposed cost limit on governmentally operated critical access hospitals (CAHs). The commenters stated that the cost limit would create a disconnect with other non-governmentally operated CAHs who would still be reimbursed at 101 percent of cost consistent with Medicare. The commenters stated that limiting the governmentally operated CAHs to 100 percent of cost would undermine their public safety net mission and could result in their inability to maintain their operations which serve a vital role in rural communities.

163R. Response: All governmentally-operated health care providers are subject to the Medicaid cost limit. Therefore, governmentally-operated critical access hospitals will be subject to the provisions of the regulation in a manner consistent with all other types of governmentally-operated health care providers. States must apply the Federal statutory and regulatory criteria to each individual health care provider within the State to make initial determinations of governmental status.

It is important to note that non-governmentally-operated health care providers, including many of the ''public'' safety net health care providers referenced by the commenters, are not affected by the Medicaid cost limit provision of the regulation and may, therefore, continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements.

164C. Comment: A number of commenters stated that this rule is administratively burdensome because school-based providers will be challenged to document costs in a cost report, which could drain school resources and may also result in medically necessary and allowable services not being reimbursed. Concern was also expressed that the regulation's documentation requirements would strain relationships between schools and school-based providers. One commenter stated that the provisions of the regulation would cause significant hardship on school district accounting offices because they are subject to Federal, State, and local regulations for accounting that are different from procedures proposed in §§ 433, 447, and 457. This commenter did not specify which Federal, State, or local accounting provisions are in conflict with the proposed provisions of the regulation. Another commenter expressed the view that a ''one size fits all'' approach to cost reporting for school based services would unnecessarily burden schools in a State where cost documentation is already accessible and verifiable.

164R. Response: For school-based services in Medicaid, we recognize that a nationally recognized, standard cost report does not currently exist, leaving States and school districts to themselves to document costs however they deem appropriate. These different practices often make it difficult to (1) align claimed expenditures with specific services covered under the State plan or identifiable administrative activities; (2) properly identify the actual cost to the governmental entity of providing services to Medicaid individuals or performing administrative activities; and (3) audit and review Medicaid

claims to ensure that Medicaid payments are appropriately made. School-based services have been cited by the Office of the Inspector General as an area within Medicaid cited for problematic claims. To ensure the fiscal integrity of the Medicaid program, we believe it is important for schools to be subject to the same requirements to document Medicaid costs as other governmental providers.

We will be publishing a standardized non-institutional services cost reporting form that can be used for school-based services in order to have such services documented in a uniform manner across the country. This standardized form should minimize the burden associated with the review of expenditures for school-based services. We expect that States with currently accessible and verifiable cost documentation will find it easier to transition into use of the new school-based services cost report template.

165C. Comment: A few commenters requested clarification regarding the inapplicability of the proposed cost limit to the State Children's Health Insurance Program (SCHIP). The commenters stated that it was unclear whether CMS was creating a new definition for what will be considered an SCHIP provider. The commenters noted that for States that have designed their SCHIP program as a Medicaid expansion, there is no distinction made between those providers who provide services to the SCHIP population and those who provide services to Medicaid enrollees. Specifically the commenters questioned that if a State's Medicaid providers are considered SCHIP providers, are they exempt from the proposed cost limit. The commenters also questioned whether if a State's Medicaid providers are not considered to be SCHIP providers and have to meet the proposed cost limit, should the State for those providers exclude SCHIP costs and reimbursements when making the Medicaid cost limit and overpayment determination. The commenters stated that if the SCHIP costs and reimbursements are not excluded, then a cost shift has occurred to the States for the difference between the State's regular FMAP rate and the enhanced SCHIP FMAP.

Another commenter expressed concern that those States which opted to implement SCHIP as a Medicaid expansion are being retroactively penalized for not implementing SCHIP as a stand alone program. This commenter stated that given the SCHIP implementation options included in the statute, this proposed regulation must clearly define the criteria and characteristics of what is; and, what is not an SCHIP provider for application of the regulation's provisions. For example, the commenter questioned whether providers are considered SCHIP providers when they provide the same service package to both Medicaid and SCHIP eligibles and are reimbursed at the same payment rates.

165R. Response: We are not creating a new definition of what is considered an SCHIP provider. We are clarifying that the provisions of this regulation are applicable to health care providers that receive payments under a separate state SCHIP, with the exception of the provisions related to the Medicaid cost limit as described below.

To the extent a State's SCHIP program is established as a Medicaid expansion program, payments to governmentally-operated health care providers for SCHIP individuals are Medicaid payments and are subject to the Medicaid cost limit. If a State operates its SCHIP program as an SCHIP stand-alone program, payments to governmentally-operated health care providers are not subject to the Medicaid cost limit. This distinction is consistent with the different nature of a separate State SCHIP and a Medicaid expansion. A Medicaid expansion is an integral part of the Medicaid program, subject to all Medicaid requirements, including beneficiary protections and payment limitations. A separate State SCHIP is not part of the Medicaid program and affords States greater flexibility, particularly in the area of provider payment and beneficiary protections. Only certain specified Medicaid requirements apply including, at section 2107(e)(1)(C), the Medicaid provider tax and donation restrictions of section 1903(w). CMS has interpreted this to include restrictions on non-governmental providers participating in the financing of the program. As a result, this rule would make applicable to separate State SCHIPs all requirements other than the Medicaid cost limits.

The regulation does not make a distinction between what is and is not an SCHIP provider. Rather the determining factor is the structure of the State's SCHIP program and what type of payments (for example, Medicaid expansion or SCHIP stand-alone) are received by governmentally-operated health care providers for individuals covered under SCHIP.

E. Retention of Payments (§ 447.207)

166C. Comment: One commenter questioned whether it is allowable for the State to retain the federal share of a supplemental Medicaid payment when the Federal share is used to support the Medicaid reimbursement, thus eliminating the need for a reduction in the Medicaid reimbursement.

166R. Response: No. Section 447.207 requires that health care providers receive and retain the full amount of the total computable payment provided to them for services furnished under the approved Medicaid State plan. Federal financial participation (FFP) is provided only when there is a corresponding State expenditure for a covered Medicaid service provided to a Medicaid individual. FFP is based on statutorily-defined percentages of total computable State expenditures for medical assistance provided to individuals under the approved Medicaid State plan, and of State expenditures related to the cost of administering the Medicaid State plan. If the State expenditure is reduced, then the Federal share of that expenditure is also proportionately reduced.

167C. Comment: A couple of commenters stated that the proposed retention of payment provisions violate section 1903(w)(6)(A) of the Act which specifically allows intergovernmental transfers and section 5 of Pub. L. 102–234, which prohibits the Secretary from changing the treatment of public funds as a source of the State share of Medicaid expenditures. The commenters also noted that Congress prohibited the Secretary from promulgating interim regulations changing the treatment of IGTs. The commenters suggested that the term ''retain'' is not defined, thus leaving the final determination of its meaning to the discretion of the Secretary. One commenter stated that this proposed provision has constitutional implications under the takings clause of the U.S. Constitution that would result if private health care providers could not freely transfer their payments from Medicaid (that is, use those payments to pay the health care provider's own expenses). One of the commenters argued that there was no reason for Congress to have inserted the phrase ''regardless of whether the unit of government is also a health care provider'' in section 1903(w)(6)(A) of the Act if it had not intended to continue to allow governmentally-operated health care providers to refund Medicaid payments, which are derived from State taxes, to the State. The commenter acknowledged that such refunds have allowed some States to pay for costs that are outside the Medicaid program, the commenter believed this was expressly permitted by Congress.

167R. Response: We have revised the language of 447.207 to make clear that

the requirement applies to States and State payment methodologies for Medicaid services and precludes States from adopting payment methodologies that involve conditional or theoretical payments to providers.

The provision at § 447.207 requiring that health care providers actually receive and retain the full amount of the total computable payment provided for services furnished under the approved State plan is consistent with section 1903(w)(6)(A) of the Act because that provision protects only those IGTs that are ''derived from State or local taxes (or funds appropriated to State university teaching hospitals).'' Since this regulation addresses only the use of Medicaid revenues, not State or local taxes, there is no conflict.

This provision specifically addresses those instances in which States make claims that are based on health care provider payments that are never actually made, are based on amounts paid with such conditions that the health care provider never actually becomes the beneficial owner of the funding (for example, when the health care provider is required to return the funding to a State agency or State directed purpose), or are otherwise diverted from use for Medicaid services by operation of law, contract or other mechanism. When the health care provider is not permitted to receive and retain the funds, the regulation would reflect the fact that the health care provider is acting simply as a conduit or agent rather than a recipient of a Medicaid payment. This means that there is no actual expenditure for Medicaid purposes.

168C. Comment: One commenter detailed that funds from governmentally-operated health care providers have been essential to States for financing health care to indigent populations. The commenter further stipulated since section 1903(w)(6)(A) of the Act protects IGTs, it specifically allows governmentally-operated health care providers to return funds in order to provide access to health care for uninsured individuals. Prohibiting governmentally-operated health care providers from doing so would necessarily reduce funds available to provide health care services to these vulnerable individuals.

168R. Response: Section 1903(w)(6)(A) of the Act protects only those IGTs that are ''derived from State or local taxes (or funds appropriated to State university teaching hospitals).'' Since this regulation addresses only the use of Medicaid revenues, not State or local taxes, there is no conflict. This regulation would not affect the ability of governmentally-operated health care providers to make IGTs that are ''derived from State or local taxes.''

169C. Comment: Numerous commenters stated that the proposed rule lacked the specificity necessary to make this provision enforceable and the commenters were unclear how a health care provider could retain the full amount of its total Medicaid payments. Most commenters questioned whether this required providers to place all Medicaid revenues in a separate account and never use Medicaid revenues to cover routine business operating expenses, such as employee salaries or purchase of supplies. These commenters felt the provision as written is unworkable and the commenters demanded clarification as to how a health care provider would comply. The commenters also stated that CMS is attempting to regulate providers' use of the Medicaid revenues that they have earned for the Medicaid services already provided. The commenters further stated that the examination of the underlying Medicaid expenditures does not provide clarity as it fails to state the standards that will be applied in such an examination. Finally, the commenters argued that this provision is especially egregious when applied to public health care providers that are now limited to cost. These providers will have already spent the full amount on services and will have nothing left to be ''retained''. One commenter recommended that the regulation make clear that the requirement to retain a payment does not prohibit them from spending earned revenue and that CMS should more clearly specify in the regulation what activities are prohibited.

In addition, these commenters specified that this requirement will not be an effective means of addressing State funding abuses. These commenters felt as though this provision is unnecessary and that if CMS is concerned that Medicaid expenditures are not consistent with legal requirements, then CMS should impose regulations on the calculation of those expenditures. Another commenter felt that this provision is also unnecessary since CMS has eliminated recycling and the purpose of the regulation is to formalize current practice, not to accomplish anything new.

Numerous other commenters requested that the authority claimed by CMS to review ''associated transactions'' be deleted. The commenters stated that this proposed requirement would prohibit providers from making expenditures with Medicaid reimbursement funds and that any routine payments from providers to State or local governmental items for items or services unrelated to Medicaid payments would come under suspicion. The commenters pointed out that financial arrangements with State and local governments require money flows for a variety of reasons. These commenters strongly argued that CMS' review and audit authority is limited to payments made under the Medicaid program and that it does not have authority over providers' use of Medicaid payments received. A few commenters requested that CMS should clarify what it considers an associated transaction in the regulation text itself. Another commenter stated that CMS has overlooked the funding realities that face public health providers and that requiring providers to retain payments may have the unintended consequence of preventing the efficient and economical flow of funding streams within and between governmental entities. Most of these commenters specified that CMS has more effective mechanisms to limit the potential for abuse involving the re-direction of Medicaid payments by IGTs. Other commenters stated that they are also concerned that CMS may use its disallowance authority to pressure public providers to dismantle such arrangements.

Another commenter stated that this requirement would be nearly impossible to track. Once funds are deposited into operating accounts, funds cannot be traced, segregated or separately identified. The commenter indicated that the proposed facility-specific cost limits would make any tracking unnecessary. The commenter argued that where a governmentally-operated health care provider is funded fully by a State or county agency, it is entirely appropriate for the provider to return to its funding agency any revenues received from payers, regardless of payer source. The commenter went on to further state that in Medicaid the governmental expenditure is always made prior to the receipt of the reimbursement and there is no valid argument that the governmental provider should not return to the original source of its expenditures the portion of the payment that was provided in the first place.

169R. Response: The retention of payments provision was broadly written in an effort to encompass the wide variety of Medicaid financing abuses that CMS has discovered over the years. In examining Medicaid State financing arrangements across the country, we have identified numerous instances in which health care providers did not

retain the full amount of their Medicaid payments, payments for which Federal matching funds were provided as a percentage of the total Medicaid payment. Instead, these health care providers returned or redirected all or a portion of the payments received, either directly or indirectly, as part of a pre-arranged agreement (contractual or otherwise) to draw additional Federal Medicaid funds that were then diverted for other purposes.

Specifically, health care providers were required to return a significant portion of a particular Medicaid payment to State or local government either directly upon receipt of such payment or indirectly through a transfer of funds in an amount greater than the non-Federal share to generate such payment. States and local governments would then use these funds to draw additional Federal matching dollars for other Medicaid payments and/or satisfy other non-Medicaid activities. In addition, health care providers were required to redirect a particular Medicaid payment to other non-Medicaid health programs to satisfy certain non-Medicaid activities, which were otherwise State only or local government only obligations often involving health care services to a non-Medicaid individual.

These arrangements are inconsistent with statutory construction that the Federal government pays its statutorily identified share of the payments for the provision of the delivery of Medicaid services. The retention of payments provision is intended to clarify the Federal government's authority to identify and correct such abuses.

The retention of payments provision was not designed to interfere with the normal operating expenses of conducting business, such as payments related to taxes, (including health-care provider-related taxes), fees, business relationships with governments unrelated to Medicaid in which there is no connection to Medicaid payment. Such normal operating expenses would not be considered ''returning/redirecting'' a Medicaid payment, we have modified the regulation to clarify this point. However, when a governmentally-operated health care provider participates in a pre-arranged agreement with the State or local government to return or re-direct a particular Medicaid payment to which it is otherwise entitled, the expenditure claimed by a State is in excess of the actual payment ultimately retained by the governmentally-operated health care provider (that is, the net expenditure). The result of such an arrangement is that the Federal government provided matching funds in excess of the net expenditure made by the State to the health care provider.

We have revised the regulation text to clarify that this requirement is not intended to burden providers, but instead is intended to be a condition for the allowability of Medicaid payment methodologies. In general, we intend to continue to focus our enforcement efforts on prospective review of proposed State payment methodologies. Indeed, this requirement should protect providers by ensuring that claimed Medicaid payments are actually available to support Medicaid services furnished by the providers.

170C. Comment: One commenter specified that CMS has indicated that an expenditure must have occurred before a unit of government can certify an expenditure to the Medicaid agency. The commenter noted that CMS has indicated that once a unit of government certifies a valid expense, the health care provider has been paid. This commenter was concerned that the proposed retention requirements make it possible for a governmental health care provider to assert it is entitled to 100 percent FFP returned to the State on the basis of its expenditure and the State's retention of any of the FFP constitutes a violation of this proposed rule. This commenter recommended that 447.207 be revised to clearly state: once a governmental health care provider certifies an expenditure, the retention of payments provisions have been satisfied; the distribution of FFP from the Medicaid agency to any certifying unit of government is not a relevant factor in measuring compliance; and the State may withhold a portion or the entire amount of FFP resulting from a CPE.

170R. Response: A certified public expenditure (CPE) means that State or local tax dollars were used to satisfy the cost of providing services to Medicaid individuals. The expenditure that is claimed for Federal matching funds based on a CPE (that is, total computable expenditure) is inherently equal to the net expenditure. The Federal matching funds, therefore, are available as a percentage of this actual certified public expenditure. Under the CPE process, a unit of government (including a governmentally-operated health care provider) has expended funds to provide services to Medicaid individuals, which means that the unit of government has satisfied both the Federal and State share of these Medicaid costs. Therefore, Federal matching funds are effectively repayment of the Federal share of the total computable expenditure initially satisfied at a State or local government level. CMS would assume that as the entity authorized to draw Federal funds, Medicaid agencies would distribute the Federal matching funds in a manner that is proportionate to the total computable expenditure by the certifying unit of government. To the extent a State agency chooses to distribute those Federal funds in a manner that is not proportional to the costs incurred by other governmental units within the State, CMS does not plan to interfere with such decisions between States, local governments and/or governmentally-operated health care providers.

171C. Comment: One commenter noted that, while not opposed to the retention of payment provision, requiring health care providers to pay the non-federal share of the Medicaid payment prior to receiving reimbursement to the State Agency will be a change to current practice. They noted that this may cause conflict with the State's prompt payment act, which requires interest to be paid to the health care provider of goods and/or services if requests for reimbursement are not paid within 45 days of receipt. The proposed rule would be an accounting burden for tracking which entities had paid and therefore appropriate to proceed with the reimbursement process.

171R. Response: Funds may be transferred by units of government that are not health care providers to the State Medicaid agency either before or after the payment to the health care provider is made, provided that the requirements of § 447.207 are satisfied. A principal concern in evaluating compliance with § 447.207 will be the determination as to whether or not the funding obligation to the non-Federal share of Medicaid payments has been fully satisfied by the State or local government. IGTs from a local or other State Agency unit of government's general fund may be considered a permissible source of the non-Federal share of Medicaid payments when: (1) Monies from the general fund are transferred to the State Medicaid agency; (2) such monies are used to fund the non-Federal share of Medicaid payments to the governmentally-operated health care provider; (3) the health care provider deposits such Medicaid payments into its operating account (a governmentally-operated health care provider will always maintain an operating account that is separate from the general fund managed by the corresponding unit of government); and (4) no portion of Medicaid payments deposited into the operating account is sent back to the general fund to replenish the loss of funds resulting from the IGT. These

conditions would demonstrate that the burden of the non-Federal share of the Medicaid payment was satisfied by the local government or other State Agency.

Governmentally-operated health care providers may only transfer funds prior to receiving a Medicaid payment. This ensures that funds were actually available to the governmentally-operated health care provider to satisfy the non-Federal share obligation to the Medicaid payment it receives and were not derived from, and effectively a reduction in, the Medicaid payment received. To permit IGTs made by a governmentally-operated health care provider after the Medicaid payment is received would effectively allow a Medicaid Agency to ''loan'' the non-Federal share obligation to the governmentally-operated health care provider. (Upon receipt of the Medicaid payment, the governmentally-operated health care provider would ''return'' the ''loan'' to the Medicaid Agency through an IGT.) The end result of a post payment IGT would be that a State is able to send Federal matching funds into a governmentally-operated health care provider without any unit of government satisfying the non-Federal share obligation. The State could then use the same funds to make additional Medicaid payments and attract new Federal matching funds.

172C. Comment: Many commenters stated that this provision is an overreaction to a concern perceived by CMS, but which it has, by its own admission, been able to deal with through the State plan or waiver approval process. The commenters are concerned that the provision would cast doubt on, if not expressly prohibit, valid fund transfers that raise no issue of ''recycling'' and involve no abuse of Medicaid funding. One commenter described how its county nursing homes are funded. The county nursing homes are financed by the county governments, which use appropriated funds to cover the nursing homes' costs of operations. The commenter noted that similar to other States and local governments, State and county tax receipts are not received in even proportions throughout the year. In order to assure funding of the nursing homes' operation during periods of slack revenues, the counties issue debt securities of which portions of the proceeds are transferred to the State to help fund Medicaid payments. Upon receipt of payments from payers, including Medicaid, the county nursing homes return funds to the counties to enable them to repay the tax anticipation notes. The commenter indicated that the counties are paying for the operations of the nursing homes with their tax dollars and the transfers from the nursing homes to the counties out of their revenues are part of a financing structure that assures a steady flow of county funds for all of the activities funded by the counties, including nursing homes. The commenter believed that as a result of the proposed rule, this appropriate financing method would be prohibited. The commenter strongly stated that this merely illustrates the damage that can be caused by overly broad federal regulations that impinge on State financial operations. Other commenters indicated that it is common practice for public providers to be funded by State and county appropriations which are returned to the State and counties after the public providers receive their federal reimbursements. The commenter strongly stated that CMS does not have the authority to declare funding arrangements between units of State government that are not prohibited by Congress to be illegitimate.

Other commenters stated that it is common for States or local governments to provide full funding to their health care providers, in the expectation of receiving the federal portion back from the health care provider when it has been reimbursed for providing Medicaid services. These commenters pointed out discrepancy between the proposed regulatory provision and preamble justification. The commenters noted that the preamble only specifies that when a governmental operated health care provider transfers to the State an amount more than the non-Federal share is there a situation where the net Medicaid payment is ''necessarily reduced.'' However the provisions of the proposed rule itself would preclude any transfer to the State from the payment received by the health care provider. The commenters questioned whether the prohibition is meant to apply to any portion of the Medicaid payment or only to the federal portion and again noted that CMS lacks any statutory basis.

Many of these commenters stated that it is more appropriate to continue to use the SPA process to deal with perceived impermissible financing arrangements and to separate the benign transfers that do not present issues of concern from those that CMS believes present problems.

172R. Response: The retention of payments provision was broadly written in an effort to encompass the wide variety of Medicaid financing abuses that CMS has discovered over the years. In examining Medicaid State financing arrangements across the country, we have identified numerous instances in which health care providers did not retain the full amount of their Medicaid payments, payments for which Federal matching funds were provided as a percentage of the total Medicaid payment. Instead, these health care providers returned or redirected all or a portion of the payments received, either directly or indirectly, as part of a pre-arranged agreement (contractual or otherwise) to inappropriately draw additional Federal Medicaid funds that are then diverted for other purposes. Other health care providers were required to return a significant portion of a particular Medicaid payment to State or local government either directly upon receipt of such payment or indirectly through a transfer of funds in an amount greater than the non-Federal share to generate such payment. States and local governments would then use these funds to draw additional Federal matching dollars for other Medicaid payments and/or satisfy other non-Medicaid activities. In addition, health care providers were required to redirect a particular Medicaid payment to other non-Medicaid health programs to help satisfy an otherwise State or local government obligation to non-Medicaid activities, often involving health care services to a non-Medicaid individual.

These arrangements are inconsistent with statutory construction that the Federal government pays its statutorily identified share of the payments for the provision of the delivery of Medicaid services. The retention of payments provision is intended to clarify the Federal government's authority to identify and correct such abuses.

The retention of payments provision was not designed to interfere with the normal operating expenses of conducting business, such as payments related to taxes, (including health-care provider-related taxes), fees, business relationships with governments unrelated to Medicaid in which there is no connection to Medicaid payment and we have modified the regulation to clarify this point. However, when a governmentally-operated health care provider participates in a pre-arranged agreement with the State or local government to return or re-direct a particular Medicaid payment to which it is otherwise entitled, the expenditure claimed by a State is in excess of the actual payment ultimately retained by the governmentally-operated health care provider (that is, the net expenditure). The result of such an arrangement is that the Federal government provided matching funds in excess of the net expenditure made by the State to the governmentally-operated health care provider.

A principal concern in evaluating compliance with § 447.207 will be the determination as to whether or not the funding obligation to the non-Federal share of Medicaid payments has been fully satisfied by the State or local government. IGTs from a local or other State Agency unit of government's general fund may be considered a permissible source of the non-Federal share of Medicaid payments when: (1) Monies from the general fund are transferred to the State Medicaid agency; (2) such monies are used to fund the non-Federal share of Medicaid payments to the governmentally-operated health care provider; (3) the health care provider deposits such Medicaid payments into its operating account (a governmentally-operated health care provider will always maintain an operating account that is separate from the general fund managed by the corresponding unit of government); and (4) no portion of Medicaid payments deposited into the operating account is sent back to the general fund to replenish the loss of funds resulting from the IGT. These conditions would demonstrate that the burden of the non-Federal share of the Medicaid payment was satisfied by the local government or other State Agency.

173C. Comment: Several commenters noted that § 447.207 is too broad. The commenters cited that the preamble to the proposed rule suggests that this retention of payments requirement only applies to IGT funded Medicaid payments, but the regulation text appears to apply to all Medicaid payments to all types of providers. The commenters requested clarification. Numerous commenters requested clarification as to whether the retention of payment provision applies to payments funded by CPEs. The commenters also stated that CMS should require States to pay all Federal funding associated with CPEs to the provider. The commenters presume that the requirement that providers ''receive and retain the full amount of the total computable payment provided to them'' applies to all payments, regardless of funding source. On the other hand, other commenters requested that CMS clarify in the regulation text that this proposed provision does not apply to services that are financed through CPEs. Another commenter requested that § 447.207 be clarified to indicate that the provisions are only applicable to payments funded with an IGT. One other commenter expressed confusion that this proposed provision appears to preclude CPEs by a governmental provider. The commenter specifically mentioned that a governmentally-operated health care provider that expends funds for salaries, utilities, food, etc. in the provision of medical services and certifies an expenditure eligible for FFP will not receive a payment.

173R. Response: Section 447.207 applies to all health care providers receiving Medicaid payments, whether such payments are funded by a State's General Fund, or by local governments including governmentally-operated health care providers via IGTs. The retention of payments provision was written specifically to address abuses involving the misuse of intergovernmental transfers. CMS has noted many instances where, under the guise of the IGT process, providers refunded or returned a portion of the payments received, either directly or indirectly, as part of an intentional scheme to inappropriately draw additional Federal Medicaid funds that are then diverted for purposes unrelated to Medicaid. Such IGT abuses occur when the State's claimed expenditure, which serves as the basis for FFP, is actually more than the State's true net expenditure, resulting in an excessive draw of Federal matching funds.

A certified public expenditure (CPE) means that State or local tax dollars were used to satisfy the cost of providing services to Medicaid individuals. The expenditure that is claimed for Federal matching funds based on a CPE (that is, total computable expenditure) is inherently equal to the net expenditure. The Federal matching funds, therefore, are available as a percentage of this actual certified public expenditure. Under the CPE process, a unit of government (including a governmentally-operated health care provider) has expended funds to provide services to Medicaid individuals, which means that the unit of government has satisfied both the Federal and State share of these Medicaid costs. Therefore, Federal matching funds are effectively repayment of the Federal share of the total computable expenditure initially satisfied at State or local government level. CMS would assume that as the entity authorized to draw Federal funds, Medicaid agencies would distribute the Federal matching funds in a manner that is proportionate to the total computable expenditure by the certifying unit of government. To the extent a State agency chooses to distribute those Federal funds in a manner that is not proportional to the costs incurred by other governmental units within the State, CMS does not plan to interfere with such decisions between States, local governments and/or governmentally-operated health care providers.

Under the provisions of the regulation, all health care providers maintain some level of ability to participate in the certified public expenditure (CPE) process. Governmentally-operated health care providers are able to certify their costs without having to demonstrate that State or local tax dollars were used to provide Medicaid services. This policy is based on the fact that governmentally-operated health care providers always have the ability to access State and/or local tax dollars as an integral component of State or local government. Governmentally-operated health care providers need only produce cost documentation via national, standardized cost reporting to receive Federal matching funds as a percentage of such allowable Medicaid (and DSH) costs.

Non-governmentally-operated health care providers may also produce cost documentation to support the costs of providing services to Medicaid individuals (and certain uninsured costs for purposes of Medicaid DSH payments). However, in order to maintain consistency with the Federal statutory instruction governing CPEs, a State or local government must actually certify that tax dollars were provided to the non-governmentally-operated health care provider. Federal matching funds will be available as a percentage of the allowable Medicaid costs incurred by the non-governmentally-operated health care provider up to the level of such State and/or local tax support.

174C. Comment: One commenter noted that CMS suggests compliance with this proposed provision may be demonstrated by showing that the funding source of an IGT is clearly separated from the Medicaid payment received by the health care provider. The commenter stated that this is an example of CMS' definition of IGT not being consistent with CMS' current practice. The commenter stated that CMS previously considered funds transferred from a State agency to the State Medicaid agency as an IGT. The commenter believed that this in fact constitutes an intragovernmental transfer within the same unit of government and therefore CMS has no authority to evaluate these transfers with the same level of scrutiny as an intergovernmental transfer. The commenter requested that CMS clarify its intent that segregation of funds does not apply to intragovermental transfers.

The commenter also stipulated that requiring a transfer within the same unit

of government must take place prior to a Medicaid payment and that the non-federal share must originate from taxes from an account that is separate from the account that receives the Medicaid payment is too restrictive. The commenter detailed that government accounting principles, established by GASB, encourage States to use the least number of funds that are necessary to comply with legal operating requirements. Another commenter noted that consolidated accounts facilitates good internal accounting controls, while also lowering overall banking costs and assisting with managing various automated transactions. The commenter also noted that any requirement to maintain separate banking accounts for tax and non-tax funds adds a burden and cost to providers without adding any benefit. The commenter suggested that a State's compliance with GASB standards in accordance with generally accepted accounting principles and a State agency's compliance with all applicable laws, rules and regulations with respect to fund accounting and budgeting should provide sufficient accountability.

174R. Response: Neither the Medicaid statute nor Federal regulation uses the term ''intragovernmental transfer.'' For purposes of the Medicaid statute, a transfer of funding between any governmental entity within a State to the State Medicaid Agency is considered an intergovernmental transfer, regardless of whether or not those entities are operated by the same unit of government (for example, a State Department of Mental Health transferring funds to a State Medicaid agency). This interpretation is consistent with the interpretation that an expenditure can be made through payment for services furnished by such an entity.

A principal concern in evaluating compliance with § 447.207 will be the determination as to whether or not the funding obligation to the non-Federal share of Medicaid payments has been fully satisfied by the State or local government. IGTs from a local or other State Agency unit of government's general fund may be considered a permissible source of the non-Federal share of Medicaid payments when: (1) Monies from the general fund are transferred to the State Medicaid agency; (2) such monies are used to fund the non-Federal share of Medicaid payments to the governmentally-operated health care provider; (3) the health care provider deposits such Medicaid payments into its operating account (a governmentally-operated health care provider will always maintain an operating account that is separate from the general fund managed by the corresponding unit of government); and (4) no portion of Medicaid payments deposited into the operating account is sent back to the general fund to replenish the loss of funds resulting from the IGT. These conditions would demonstrate that the burden of the non-Federal share of the Medicaid payment was satisfied by the local government or other State Agency.

Governmentally-operated health care providers may only transfer prior to receiving a Medicaid payment to ensure funds were actually available to the governmentally-operated health care provider to satisfy the non-Federal share obligation to the Medicaid payment it receives. To permit non-Federal share transfer obligations made by a governmentally-operated health care provider after the Medicaid payment is received would allow a Medicaid Agency to ''loan'' the non-Federal share obligation to the governmentally-operated health care provider (as described previously).

175C. Comment: A couple of commenters requested that provisions of the proposed retention of payment provisions be clarified to explicitly state that an IGT from a single governmental entity can be the basis of the State match for multiple hospitals in the eligible payment group. Another commenter asked that CMS provide additional guidance on whether a group of governmental entities could provide the IGTs for other public hospitals. The commenter was concerned that this may not be allowed under the proposed rules. The commenter suggested that this clarification would be consistent with CMS'' overall objective that IGTs are used to reimburse hospitals for the care of Medicaid individuals and are not ''retained'' by local governments. One commenter was concerned that this proposed provision would require that all government providers provide their own IGT in return for the Medicaid payment.

175R. Response: The provisions at § 447.207 were not intended to suggest that a unit of government can only transfer funding to the State for specific use in State Medicaid payments made to the unit of government itself. In fact, a unit of government may permissibly transfer funds to be used for the non-Federal share of State Medicaid payments made to other health care providers within the State, regardless of whether or not such providers are related to the unit of government transferring the funds, assuming all other financing requirements are satisfied, including compliance with section 1902(a)(2) of the Act. Governmentally-operated health care providers may also transfer funding for other health care providers, but each transfer must be transacted on an individual basis per each Medicaid payment to each health care provider to ensure compliance with sections 1902(a)(30)(A) and 1903(w)(6)(A) of the Act. Moreover, a governmentally-operated health care provider that is subjected to more than one non-Federal share obligation must transact each IGT obligation on an individual basis per Medicaid payment to which it is entitled in order to maintain consistency with sections 1902(a)(30)(A) and 1903(w)(6)(A) of the Act.

176C. Comment: One commenter stated that health care providers may be subject to taxation, licensing, and other fees that are generally applied to the private sector or to the health care industry at large. The commenter was concerned that the proposed rule would enable providers to assert that they should not be subject to normal operating expenses, which have no direct connection to Medicaid, in as much as they are required to retain the full amount of the total computable payment. The commenter specifically requested that proposed § 447.207 be clarified to clearly state that normal operating expenses are not affected by the retention requirements and are not included in the calculation of a State's net expenditures.

176R. Response: The retention of payments provision was written to address instances where health care providers did not retain the full amount of their Medicaid payments, payments for which Federal matching funds were provided as a percentage of the total Medicaid payment. Instead, these providers returned or redirected all or a portion of the payments received, either directly or indirectly, as part of a pre-arranged agreement (contractual or otherwise) to draw additional Federal Medicaid funds that were then diverted for other purposes. The retention of payments provision was not designed to interfere with the normal operating expenses of conducting business, such as payments related to taxes (including health-care provider-related taxes), fees, business relationships with governments unrelated to Medicaid in which there is no connection to Medicaid payment. Such normal operating business expenses would not be considered ''returning/redirecting'' a Medicaid payment and we have modified the regulation to clarify this point.

177C. Comment: A few commenters stated the proposed requirement to retain full payments conflicts with section 1903(w) of the Act. The commenters noted that section 1903(w) of the Act clearly contemplates that providers can return certain portions of payments as bona fide donations and permits certain qualifying health care taxes. The commenters requested that proposed § 447.207 be modified to clearly allow donations and taxes as permitted by section 1903(w) even if a Medicaid payment is the source of those donations or tax payments.

177R. Response: We concur with this comment in part and we are clarifying the provisions at § 447.207. We agree that governmentally-operated health care providers may make bona fide donations, and may be subject to qualifying health care taxes, from the amount of their total computable Medicaid payment. Qualifying health care taxes would be an allowable cost of services furnished under the approved State plan for purposes of this section and for the cost limits under § 447.206. Bona fide donations, on the other hand, would not be an allowable cost of Medicaid services under either section, but we would clarify that under § 447.207, a provider could make a bona fide donation (which by definition could not be linked to the receipt of, or amount of a Medicaid payment). While we agree to make this clarification, there does not appear to be a practical effect to this clarification since, under § 447.206, Medicaid payments to governmentally-operated health care providers must still be equal or less than the costs incurred by the governmentally-operated health care provider for covered Medicaid services.

178C. Comment: One commenter stated that CMS assumes that any requirement that a governmentally-operated health care provider transfer more than the non-federal share of a Medicaid payment means that Medicaid payments to that provider are not retained. The commenter indicated that CMS is linking two independent actions that should not be linked. The commenter specified that once a governmental unit transfers funds to the State, it is up to the State to do what it deems appropriate with the funds. The commenter argued that it is not within the authority of the governmental unit or CMS to dictate what the State can do with the funds. In fact, the commenter went on to state, once the State uses the funds to make allowable Medicaid payments, such use falls within section 1902(a)(30)(A) of the Act and FFP is appropriate. The commenter believes that it does not matter what level of Medicaid payment the State is making or to which providers; FFP should apply in its normal proportion. The State's net expenditure is determined by the amount paid under the terms of its approved State plan, not by the sources of funds used to finance that plan.

178R. Response: The provision at § 447.206 would require that health care providers retain the full Medicaid payment, including both Federal and non-Federal shares. As discussed above, protected IGTs are limited to those ''derived from State or local taxes (or funds appropriated to State university teaching hospitals).'' There is no protection for IGTs derived from Medicaid payments to health care providers. But we are clarifying that § 447.207 is not intended to dictate what the health care provider may do with its own funds; it concerns solely the circumstances in which CMS will recognize a payment to the provider as an allowable expenditure. This provision specifically addresses those instances in which States make claims that are based on health care provider payments that are never actually made, are based on amounts paid with such conditions that the health care provider never actually becomes the beneficial owner of the funding (for example, when the health care provider is required to return the funding to a State agency or State directed purpose), or are otherwise diverted from use for Medicaid services by operation of law, contract or other mechanism. When the health care provider is not permitted to receive and retain the funds, the regulation would reflect the fact that the provider is acting simply as a conduit or agent rather than a recipient of a Medicaid payment. This regulation ensures that payments are made for Medicaid purposes and not obligated for other purposes. This regulation also ensures that claimed payments are not sham transactions in which the State (or other payor) has never actually ceded control of the funds to the health care provider.

179C. Comment: Several commenters stated that it is unclear how CMS will enforce proposed § 447.207.

179R. Response: In general, CMS intends to continue to focus enforcement efforts on prospective review of proposed State payment methodologies. This regulation, however, would provide a basis to pursue other enforcement measures, such as disallowance of claimed expenditures, should prospective enforcement prove inadequate. States can appeal such enforcement actions through existing appeal processes.

180C. Comment: One commenter noted language concerning IGTs in the preamble that was not included in the actual regulatory text. Specifically, the commenter observed the following preamble language: ''* * * [C]laimed expenditures must be net of any redirection or assignment from a health care provider to any State or local governmental entity that makes IGTs to the Medicaid agency. Generally, for the State to receive Federal matching on a claimed Medicaid payment where a governmentally-operated health care provider has transferred the non-Federal share, the State must be able to demonstrate: (1) That the source of the transferred funds is State or local tax revenue (which must be supported by consistent treatment on the provider's financial records); and (2) that the provider retains the full Medicaid payment and is not required to repay, or in fact does not repay, all or any portion of the Medicaid payment to the State or local tax revenue account.'' Further, the commenter noted this language in the preamble: ''Therefore, we have concluded that requirements that a governmentally-operated health care provider transfer to the State more than the non-Federal share of a Medicaid payment creates an arrangement in which the net payment to the provider is necessarily reduced; the provider cannot retain the full Medicaid payment claimed by the State.'' The commenter opined that this preamble language should be specifically included in the appropriate sections of the regulations.

180R. Response: We agree that the regulation should contain more specific language on prohibited arrangements, and we have modified the regulation as appropriate.

181C. Comment: One commenter inquired as to how the proposed retention of payments provision impacts ''administrative fees'' for operation of targeted case management programs which are offset against amounts paid for services. The commenter asked if such fees would be prohibited and, if not, whether an offset against Medicaid payments due would continue to be permissible.

181R. Response: Administrative fees are sometimes deducted by the Medicaid agency, or other agency making Medicaid payments, from the Medicaid payment to a provider. These fees represent a reduction in the allowable Medicaid expenditure that can be claimed for purposes of FFP. Moreover, while FFP is available for actual administrative costs, FFP is not available for administrative fees. The Medicaid program's share of actual administrative costs should be claimed

pursuant to an approved cost allocation plan by the agency that incurs those actual administrative costs.

Administrative costs and medical service costs are separately recognized in the Medicaid statute for purposes of Federal financial participation (FFP). Administrative costs and medical service costs must also be separately reported on the CMS 64 report for purposes of State expenditures eligible for FFP.

An arrangement in which administrative costs are offset from a medical service payment has two major problems: (i) Administrative costs are effectively matched with Federal funds at the FMAP rate instead of the 50 percent administrative matching rate; and, (ii) the governmentally-operated health care provider realizes a net reduction to its Medicaid medical service payment because it must redirect a portion of the Federal funding associated with the Medicaid medical service payment it receives to pay another agency for administrative costs.

In some instances, a mandatory assessment or ''fee'' imposed on a health care provider could be viewed as a health care-related tax. All health care-related taxes must meet the specified statutory criteria, including the broad based requirement to avoid penalties against a State's Medicaid expenditures. The broad based provision of the statute requires that all health care providers of the service must be subject to the tax or ''fee.''

F. Upper Limits Based on Customary Charges (§ 447.271)

182C. Comment: Several commenters objected to the proposed modifications at § 447.271 to delete the exception for nominal charge hospitals. Paragraph (b) of this section allowed public providers that provide services ''free or at a nominal charge'' to be paid to the level that would be set ''if the provider's charges were equal to or greater than its costs.'' The commenters noted that this existing exception recognizes that there are many hospitals that primarily serve the poor and uninsured. These hospitals have set their charges at low levels for the uninsured individuals to help alleviate these individuals from exorbitant hospital bills. The commenters argued that a hospital should not be disadvantaged with respect to Medicaid reimbursement just because it was willing to keep the cost of hospital care within reason for those who do not have coverage from insurance or public programs. The commenters urged CMS to maintain this exception.

Another commenter disagreed that § 447.271(b) becomes irrelevant due to the proposed cost limit. The commenter stated that the existing regulation at § 447.271(b) is related to limitations based on provider charges not provider costs and allows Medicaid payments in excess of a provider's charges if those charges are nominal or do not exist. The commenter argued that eliminating this regulatory provision would restrict Medicaid reimbursement to nominal charge providers or require them to implement unnecessary or artificial charge structures.

Another commenter stated that with this elimination, nominal charge providers would be limited to charges as its total payment. The commenter argued the proposed cost limit does not affect the operation of the charge limit rule where charges are less than cost and should be maintained.

182R. Response: We do not read the customary charge limitation at § 447.271(a) to preclude a health care provider from offering services on a sliding scale or reduced rate basis (or even free) to poor and uninsured patients. All health care providers can or should have customary charge schedules that represent the undiscounted amount charged to third party payers and individuals with sufficient resources. We do not believe it would be consistent with efficiency or economy for Medicaid to pay more for services than other payers with sufficient resources. Thus we do not see a reason for an exception to the customary charge limit. In the unlikely event that a health care provider does not have a customary charge structure the health care provider can receive payments in an amount equal to the cost of providing services subject to applicable payment limits depending upon their governmental status. We further do not see any statutory basis to permit payment in excess of costs to support non-Medicaid uncompensated care activities. In the Medicaid statute, Congress has specifically provided for a mechanism to address uncompensated care costs for disproportionate share hospitals, but has imposed clear limits on that mechanism. It would be inconsistent with those statutory limits to continue to provide a different avenue to address the same types of costs without any statutory authorization to do so.

183C. Comment: One commenter requested that in accordance with Medicare and other Federal regulations, CMS should make it clear that the customary charge limit and existing UPL requirements do not apply to critical access hospitals. The commenter stated that since the customary charge limit applies to hospitals and does not specify critical access hospitals, inpatient and outpatient payment limits should not be applicable to critical access hospitals. The commenter suggested that CMS make the distinction between hospitals and critical access hospitals by either including this statement as a clarification in § 447.271 or as an exemption within §§ 447.272 and 447.321. The commenter also stated that critical access hospital regulations should be amended to prohibit States from imposing an upper limit on critical access hospital Medicaid payments. The commenter specified that while many States reimburse critical access hospitals using a cost-based reimbursement methodology, certain limitations are placed on the reimbursements. The commenters do not believe this is consistent with Medicare reimbursement methodologies.

183R. Response: All governmentally-operated health care providers are subject to the Medicaid cost limit and customary charge limit. Therefore, governmentally operated critical access hospitals will be subject to the provisions of the regulation in a manner consistent with all other types of governmentally-operated health care providers. States must apply the Federal statutory and regulatory criteria to each individual health care provider within the State to make initial determinations of governmental status. In addition, §§ 447.272 and 447.321 apply to all inpatient and outpatient hospital services, including those provided in critical access hospitals.

G. Inpatient Services: Application of Upper Payment Limits (§ 447.272) and Outpatient Hospital and Clinic Services: Application of Upper Payment Limits (§ 447.321)

184C. Comment: One commenter stated that § 447.272 includes an exception for DSH payments and Indian Health Services. The commenter noted that § 447.321 likewise includes an exception for Indian Health Services, but does not list DSH as an exception. The commenter requested that CMS include a similar exception for DSH in § 447.321. The commenter is concerned that this omission could prohibit or restrict DSH payments for outpatient hospital services.

184R. Response: We agree with the commenter, and we have modified section 447.321 to include the exemption of DSH payment adjustments from the application of outpatient hospital upper payment limits. It should

be noted that clinic costs are not eligible under the hospital-specific DSH limit, so the DSH exemption is not applicable to clinic upper payment limits.

185C. Comment: A few commenters recommended that the proposed corresponding changes to §§ 447.272 and 447.321 to reflect the proposed cost limit to governmentally operated providers be withdrawn.

185R. Response: The changes to §§ 447.272 and 447.321 are necessary to maintain consistency with the provision of the regulation limiting Medicaid payments to the full cost of providing services to Medicaid individuals.

H. Conforming Changes to Other Applicable Federal Regulations (§§ 457.220 and 457.628)

186C. Comment: A few commenters recommended that the conforming changes to §§ 457.220 and 457.628 be deleted. These commenters opined that since they believe the proposed rule is inappropriate for a variety of reasons, the conforming changes proposed would also be inappropriate.

186R. Response: Title XXI and corresponding SCHIP regulations fully incorporate Medicaid statutory and regulatory provisions concerning the source of the non-Federal share. Therefore, the regulation makes changes to SCHIP rules at §§ 457.220 and 457.628 to ensure that regulations governing the source of the non-Federal share and provider retention of payments are consistent between the Medicaid program and SCHIP. The Medicaid cost limit does not apply to governmentally-operated SCHIP health care providers.

I. Collection of Information Requirements

187C. Comment: A number of commenters communicated that they believe CMS estimates on the time needed for providers to complete cost report forms and States to review cost reports are understated. Commenters also observed that the proposed rule sets out only minimum documentation requirements, that actual forms have not yet been completed, and that it is therefore unlikely that CMS has fully assessed the extent of the paperwork burden associated with this requirement. One commenter argued that CMS estimates on time are too low by outlining the steps required to implement this provision. One commenter is familiar with the experience of public hospitals in California that are implementing cost reporting under a CMS-approved 1115 demonstration and stated that hundreds of hours have been spent attempting to implement the new CPE and cost-finding rules. Another commenter explained that providers currently spend hundreds of hours preparing and submitting Medicare cost reports.

187R. Response: In light of comments received on the estimated time required for governmentally operated providers to complete the new cost report forms and States to review the cost reports, CMS has reviewed the initial estimates for these activities. The revised estimates will accompany the publication of the cost report template in the **Federal Register**.

However, we do not believe the Medicaid cost limit will impose significant administrative burden on States particularly since the limit applies only to governmentally-operated health care providers.

For purposes of institutional governmentally-operated health care providers, the Medicaid cost limit determination will rely on existing reporting tools used by institutional health care providers. States will not be required to audit financial and cost information provided by individual institutional governmentally-operated health care providers as part of the Medicaid cost limit review. Each of the source documents is subject to reporting and auditing rules specific to the original purpose of that document and independent of the Medicaid cost limit and State review process. The State must render an determination on the cost limit methodology applied to the source documents but will not be required to validate the accuracy of the information and data within the source documents.

For non-institutional services provided to Medicaid eligible individuals, a nationally recognized, standard cost report currently does not exist. Because of this, we will be publishing a standardized cost reporting form that should be used to document such services. The purpose of this standardized form is to document in a uniform manner the cost of providing non-institutional services to Medicaid individuals. The period of time to which this cost report applies will be the Medicaid State plan rate year.

CMS has modified the regulation to include a transition period to allow States and governmentally operated non-institutional health care providers sufficient time to develop and implement Medicaid cost documentation and reporting processes consistent with the cost report template issued by CMS (including but not limited to changes in State/provider reporting systems, changes to the Medicaid State plan, changes to time studies, establish periodic review and audit processes, etc.), States will not be required to document and report cost information associated with non-institutional Medicaid services until the State's Medicaid State plan rate year 2009. Actual submission of the State's summary report on the Medicaid cost limit for non-institutional services will not be due to CMS until December 31, 2011, which allows States an opportunity to implement periodic review and audit processes for Medicaid non-institutional costs starting in Medicaid State plan rate year 2009.

CMS has developed a general Medicaid Cost Reporting Protocol available on the CMS Web site that specifically addresses the methods under which institutional and non-institutional Medicaid costs will be determined. The protocol was designed to provide States with detailed instructions to determine compliance with Federal requirements.

188C. Comment: One commenter identified the ''unfunded workloads'' for State agencies resulting from the proposed rule. The increased workload was attributed to the rule's requirements that State agencies collect, review, and audit cost reports from governmental providers; document their own costs to the extent they are providers themselves; and obtain and review information from purportedly governmental providers using the ''Tool to Evaluate the Governmental Status of Providers'' form. The commenter expressed concern that an unintended consequence of this additional workload could be that State and local governments have to reduce the delivery of services.

188R. Response: We do not believe the cost limit will impose significant administrative burden on States particularly since such limit applies only to governmentally-operated health care providers.

For purposes of institutional governmentally-operated health care providers, the Medicaid cost limit determination will rely on existing reporting tools used by institutional health care providers. States will not be required to audit financial and cost information provided by individual institutional governmentally-operated health care providers as part of the Medicaid cost limit review. Each of the source documents is subject to reporting and auditing rules specific to the original purpose of that document and independent of the Medicaid cost limit and State review process. The State must render a determination on the cost limit methodology applied to the source documents but will not be required to

validate the accuracy of the information and data within the source documents.

For non-institutional services provided to Medicaid eligible individuals, a nationally recognized, standard cost report currently does not exist. Because of this, we will be publishing a standardized cost reporting form that should be used to document such services. The purpose of this standardized form is to document in a uniform manner the cost of providing non-institutional services to Medicaid individuals. The period of time to which this cost report applies will be the Medicaid State plan rate year.

CMS has modified the regulation to include a transition period to allow States and governmentally operated non-institutional health care providers sufficient time to develop and implement Medicaid cost documentation and reporting processes consistent with the cost report template issued by CMS (including but not limited to changes in State/provider reporting systems, changes to the Medicaid State plan, changes to time studies, establish periodic review and audit processes, etc.), States will not be required to document and report cost information associated with non-institutional Medicaid services until the State's Medicaid State plan rate year 2009. Actual submission of the State's summary report on the Medicaid cost limit for non-institutional services will not be due to CMS until December 31, 2011, which allows States an opportunity to implement periodic review and audit processes for Medicaid non-institutional costs starting in Medicaid State plan rate year 2009.

CMS has developed a general Medicaid Cost Reporting Protocol available on the CMS Web site that specifically addresses the methods under which institutional and non-institutional Medicaid costs will be determined. The protocol was designed to provide States with detailed instructions to determine compliance with Federal requirements.

189C. Comment: With respect to the ''Tool to Evaluate the Governmental Status of Providers'' form, one commenter said that CMS failed to set out a satisfactory analysis of alternative approaches to obtaining the information that is necessary to determine compliance with the proposed regulations. The commenter raised this issue because in order to obtain OMB approval for a collection of information, CMS must show that its proposal is the least burdensome option necessary for the proper performance of the agency's functions. Moreover, the commenter questioned the practical utility of this form because it ''attempts to face a complex legal analysis into a Q&A format'' and does not provide any explanation as to the consequences of answers.

189R. Response: The ''Tool to Evaluate the Governmental Status of Health Care Providers'' is designed to guide State decision making in applying the statutory and regulatory criteria regarding units of government. The provisions of the regulation were designed to ensure consistent application of the Federal statutory instructions regarding the definition of a unit of government for purposes of Medicaid reimbursement and State financing. CMS recognizes that States play a major role in the administration of the Medicaid program and that legal and financial arrangements between health care providers and units of government vary on a case by case basis. We have developed standardized and impartial regulatory criteria based upon Federal statute that States must apply on a consistent basis to each health care provider within the State.

We believe the tool is useful to States and actually reduces the State's burden by putting complex statutory and regulatory standards into a practical and user friendly format.

J. Regulatory Impact Analysis

190C. Comment: Many commenters offered opinions about the estimated financial impact the proposed rule would have on a particular State. These monetary estimates varied widely from one State to another, but the commenters consistently expressed that the loss of Federal funding that would result from this rule would create large funding gaps that would have to be addressed by State and local governments. Commenters asserted that States and local governments would not necessarily have the revenues to fill these gaps, and as a result, they may choose to cut reimbursements to providers, eliminate Medicaid individuals from their programs, or reduce the scope of covered benefits. None of these alternatives was viewed favorably by the commenters.

190R. Response: Medicaid is a shared responsibility between Federal and State government. State governments may share their fiscal obligation to the Medicaid program with local governments according to the instruction of Congress. Under Public Law 102–234, the Congress made clear that States may allow governmentally-operated health care providers to participate in a State's fiscal obligation to the Medicaid program through the use of intergovernmental transfers and certified public expenditures. However, the Congress was also clear that States may not receive funds from non-governmentally-operated health care providers for purposes of financing Medicaid payments.

The provision of the regulation that addresses a unit of government codifies the existing statutory definitions of a unit of government. This codification of existing Federal statute was established in an effort to assist States in identifying the universe of governmentally-operated health care providers that could receive Medicaid revenues up to the full cost of providing services to Medicaid individuals and clarifies which types of health care providers can participate in financing of the non-Federal share of Medicaid payments.

Medicaid is a vitally important program that serves very vulnerable individuals, and the Federal government remains committed to funding its share of the cost of providing Medicaid services to eligible individuals. We also note that State decisions will be the major factor in the actual financial impact this regulation will have within each State. CMS recognizes that States play a major role in the administration of the Medicaid program and that legal and financial arrangements between health care providers and units of government vary on a case by case basis. Therefore, CMS has developed standardized and impartial regulatory criteria based upon Federal statue that States must apply on a consistent basis to each health care provider within the State to determine whether or not the health care provider is considered a unit of government under the regulation.

Non-governmentally-operated health care providers, including many of the ''public'' safety net health care providers, are not affected by the cost limit provision of the regulation and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements.

Moreover, the regulation reaffirms State Medicaid financing policy requiring that health care providers be allowed to fully retain their Medicaid payments, another provision of which clearly demonstrates the Federal government's intent to protect the nation's public safety net and its ability to continue delivering critical health care services to Medicaid individuals and the uninsured. Any health care providers that become ineligible to participate in the State financing of Medicaid payments following the effective date of the provisions of this

regulation can realize greater net revenues if State or local governments choose to utilize their funding sources to fund non-Federal share obligations to Medicaid payments historically financed by non-governmentally-operated ''public'' health care providers.

191C. Comment: A number of commenters thought that CMS estimates that the proposed rule would result in a $3.87 billion savings to the Federal government over the next five years was too low. The commenters asserted that the loss of Federal funds was expected to be at least $932 million in one State, $253 million in another State, $350 million in another State, and $374 million in yet another State. Commenters noted that an estimated impact over five years of $4.7 billion in one State specifically is higher than the national CMS calculation for the same period. Commenters asked CMS to reevaluate this estimate.

191R. Response: We find many of the expressed concerns about the potential impact of the cost limit to be overstated based on a misunderstanding of certain provisions of the regulation, which have been clarified in this final regulation. We also note that State decisions will be the major factor in the actual financial impact this regulation will have within each State.

The provision of the regulation that addresses a unit of government codifies the existing statutory definitions of a unit of government. This codification of existing Federal statute was established in an effort to assist States in identifying the universe of governmentally-operated health care providers that could receive Medicaid revenues up to the full cost of providing services to Medicaid individuals and clarifies which types of health care providers can participate in financing of the non-Federal share of Medicaid payments. CMS has developed standardized and impartial regulatory criteria based upon Federal statue that States must apply on a consistent basis to each health care provider within the State to determine whether or not the health care provider is considered a unit of government under the regulation.

Non-governmentally-operated health care providers, including many of the ''public'' safety net health care providers, are not affected by the cost limit provision of the regulation and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements.

Moreover, one provision of the regulation reaffirms State Medicaid financing policy requiring that health care providers be allowed to fully retain their Medicaid payments, another provision of which clearly demonstrates the Federal government's intent to protect the nation's public safety net and its ability to continue delivering critical health care services to Medicaid individuals and the uninsured. Any health care providers that become ineligible to participate in the State financing of Medicaid payments following the effective date of the provisions of this regulation can realize greater net revenues if State or local governments choose to utilize their funding sources to fund non-Federal share obligations to Medicaid payments historically financed by non-governmentally-operated ''public'' health care providers.

192C. Comment: Several commenters opined that CMS failed to adequately explain how it reached its estimate that the proposed rule would result in a $3.87 billion savings to the Federal government over the next five years. Commenters noted that in the preamble CMS acknowledged uncertainty in the estimated impact of the rule. Some of the commenters pointed out that since publication of the proposed rule, CMS has been asked for State-specific estimates of the rule's financial impact, but CMS refused to provide such estimates and stated that no such calculations had been performed. Requests for further information about how CMS produced this estimate were made, and several commenters expressed that CMS should not proceed with implementation of the rule without knowing more about the potential impact.

192R. Response: The regulation's preamble included a detailed description of the methodology utilized by CMS to develop the estimate that the regulation would result in a $3.87 billion savings to the Federal government over the next 5 years.

All States could be affected by the provisions of the regulation if the State currently:

- Reimburses governmentally-operated health care providers in excess of the cost to provide services to Medicaid individuals;
- Accepts funds from non-governmentally-operated health care providers to help fund the non-Federal share of Medicaid payments; and/or,
- Requires the return of Medicaid payments.

State-specific effects of the regulation can only be determined by the States as each State administers its own Medicaid program. We also note that State decisions will be the major factor in the actual financial impact this regulation will have within each State.

The provision of the regulation that addresses a unit of government codifies the existing statutory definitions of a unit of government. This codification of existing Federal statute was established in an effort to assist States in identifying the universe of governmentally-operated health care providers that could receive Medicaid revenues up to the full cost of providing services to Medicaid individuals and clarifies which types of health care providers can participate in financing of the non-Federal share of Medicaid payments. CMS has developed standardized and impartial regulatory criteria based upon Federal statue that States must apply on a consistent basis to each health care provider within the State to determine whether or not the health care provider is considered a unit of government under the regulation.

193C. Comment: A number of commenters suggested that CMS failed to account for the initial and ongoing costs of implementation and compliance with the proposed regulation to the federal government and to States. These commenters observed that the estimated impact to the Federal government does not appear to include offsets for new needs, including additional staff that States and the Federal government will hire, the information technology and infrastructure development and changes, and educational efforts among States, providers and other stakeholders that will be required of the Federal government. One commenter believes that the proposed regulation understates the administrative burden on providers and the indirect impact that additional provider mandates could have on States' ability to develop adequate provider networks. Another commenter estimated that more than 20,000 man hours will be required to initially comply with the regulation. Thus, commenters requested that CMS explain how it accounted for these additional costs or withdraw the rule due to the unwarranted burden associated with implementation.

193R. Response: We do not believe that compliance with the regulation will result in significant administrative costs for States. For institutional governmentally-operated health care providers, the Medicaid cost limit determination will rely on existing reporting tools used by institutional health care providers. States will not be required to audit financial and cost information provided by individual institutional governmentally-operated health care providers as part of the Medicaid cost limit review. Each of the

source documents is subject to reporting and auditing rules specific to the original purpose of that document and independent of the Medicaid cost limit and State review process. The State must render an determination on the cost limit methodology applied to the source documents but will not be required to validate the accuracy of the information and data within the source documents.

For non-institutional services provided to Medicaid eligible individuals, a nationally recognized, standard cost report currently does not exist. Because of this, we will be publishing a standardized cost reporting form that should be used to document such services. The purpose of this standardized form is to document in a uniform manner the cost of providing non-institutional services to Medicaid individuals. The period of time to which this cost report applies will be the Medicaid State plan rate year.

CMS has modified the regulation to include a transition period to allow States and governmentally operated non-institutional health care providers sufficient time to develop and implement Medicaid cost documentation and reporting processes consistent with the cost report template issued by CMS (including but not limited to changes in State/provider reporting systems, changes to the Medicaid State plan, changes to time studies, establish periodic review and audit processes, etc.), States will not be required to document and report cost information associated with non-institutional Medicaid services until the State's Medicaid State plan rate year 2009. Actual submission of the State's summary report on the Medicaid cost limit for non-institutional services will not be due to CMS until December 31, 2011, which allows States an opportunity to implement periodic review and audit processes for Medicaid non-institutional costs starting in Medicaid State plan rate year 2009.

Each State is responsible for the proper and efficient administration of its Medicaid program. Expenses incurred for administration of the Medicaid program are eligible for Federal matching funds at the at the regular 50 percent administrative matching rate.

194C. Comment: One commenter implied that based on Federal Medical Assistance Percentage (FMAP) rates, the loss of Federal funding from the rule would harm the poorest States the most, as they would have the largest funding gap to make up, dollar for dollar as a percentage of expenditures, when compared to wealthier States with lower FMAP rates.

194R. Response: Federal Medical Assistance Percentage (FMAP) rates are calculated strictly based upon the formula required by the Medicaid statute. Such calculations are outside the scope of this regulation.

Under the provisions of the regulation, governmentally-operated health care providers will be permitted to receive up to 100 percent of the cost of serving Medicaid individuals. We are unclear how limiting Medicaid reimbursement to the full cost or providing services to Medicaid individuals would adversely affect a governmentally-operated health care provider, unless the health care provider had been historically receiving Medicaid payments above cost and using excess Medicaid revenues to subsidize other costs outside of the Medicaid program. In such a situation, the proposed cost limit could cause a net reduction in Medicaid revenue to the health care provider, but the amount of the reduction would directly correspond with the amount of Medicaid revenues that had been used for non-Medicaid purposes.

Non-governmentally-operated health care providers, including many of the ''public'' safety net health care providers, are not affected by the cost limit provision of the regulation and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements. It remains unclear how a limit that does not apply to public hospitals could adversely impact quality and patient safety and vital community services.

Moreover, the provisions of the regulation reaffirms State Medicaid financing policy requiring that health care providers be allowed to fully retain their Medicaid payments, another provision of which clearly demonstrates the Federal government's intent to protect the nation's public safety net and its ability to continue delivering critical health care services to Medicaid individuals and the uninsured. Any health care providers that become ineligible to participate in the State financing of Medicaid payments following the effective date of the provisions of this regulation can realize greater net revenues if State or local government funding sources are utilized to fund non-Federal share obligations to Medicaid payments historically financed by non-governmentally-operated ''public'' health care providers.

195C. Comment: A number of commenters noticed that in the preamble, CMS mentioned that it examined Medicaid financing arrangements across the country but did not provide information on which States or how many States are employing questionable financing practices. Therefore, the commenters believe that the public is unable to meaningfully review the changes proposed by this rule or the estimated impact.

195R. Response: CMS has examined numerous financing arrangements across the country; however, CMS cannot be certain that it has examined all questionable Medicaid financing arrangements among all the States in the nation. Any attempt to publish a comprehensive list of questionable Medicaid financing arrangements among States would be misleading.

196C. Comment: One commenter asked specifically for any economic and other assumptions that CMS used in arriving at its estimate that the proposed rule's effect on actual patient services will be minimal.

196R. Response: The statement referenced by the commenter was based on the fact that (1) the regulation presents no changes to coverage or eligibility requirements under Medicaid; (2) the regulation clarifies statutory financing requirements and allows governmentally operated providers to be reimbursed at levels up to cost; and (3) Federal matching funds will continue to be made available based on expenditures for appropriately covered and financed services delivered to Medicaid eligible individuals. Governmentally-operated health care providers can receive Medicaid revenues up to the full cost of providing services to Medicaid individuals and private health care providers may continue to receive Medicaid revenue in excess of Medicaid cost. Under these circumstances we do not anticipate that the actual services delivered by governmentally-operated health care providers or private health care providers will change.

197C. Comment: One commenter expressed its intent to redistribute any funds that were paid to governmental providers in excess of cost to other providers that were paid less than cost, thereby negating any Federal savings that might be assumed from the cost limit provision of the regulation. In this regard, the commenter questioned the validity of any estimated Federal savings in the Regulatory Impact Analysis that is associated with the cost limit provision.

197R. Response: This comment illustrates the significance of State decision-making in determining the actual financial impact this regulation.

Under the provisions of the regulation, Federal matching funds will be made available to States for payments to governmentally-operated health care providers under the approved Medicaid State Plan, up to 100 percent of the cost of providing services to Medicaid individuals.

Non-governmentally-operated health care providers, including many of the ''public'' safety net health care providers, are not affected by the cost limit provision of the regulation and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements. Any health care providers that become ineligible to participate in the State financing of Medicaid payments following the effective date of the provisions of this regulation can realize greater net revenues if State or local governments choose to utilize their funding sources to fund non-Federal share obligations to Medicaid payments historically financed by non-governmentally-operated ''public'' health care providers.

198C. Comment: A number of commenters stated that the additional administrative workload associated with the cost limit and cost reporting for governmental providers will be excessive. One commenter believes that its State is not currently staffed to review or audit cost reports or forms of this magnitude, while another commenter stated that retrospective cost settlements of all providers considered units of government were not sufficiently accounted for in the impact analysis. One commenter, a State Medicaid agency, estimated that at least four FTEs will need to spend six months on the process of merely identifying governmental providers and making the relevant changes to the State's MMIS system. To illustrate the point on the administrative workload, one commenter listed a number of tasks that may be required to implement this provision.

198R. Response: We do not believe that compliance with the regulation will result in significant administrative costs for States. For institutional governmentally-operated health care providers, the Medicaid cost limit determination will rely on existing reporting tools used by institutional health care providers. States will not be required to audit financial and cost information provided by individual institutional governmentally-operated health care providers as part of the Medicaid cost limit review. Each of the source documents is subject to reporting and auditing rules specific to the original purpose of that document and independent of the Medicaid cost limit and State review process. The State must render an determination on the cost limit methodology applied to the source documents but will not be required to validate the accuracy of the information and data within the source documents.

For non-institutional services provided to Medicaid eligible individuals, a nationally recognized, standard cost report does not currently exist. Because of this, we will be publishing a standardized cost reporting form that should be used to document such services. The purpose of this standardized form is to document in a uniform manner the cost of providing non-institutional services to Medicaid individuals. The period of time to which this cost report applies will be the Medicaid State plan rate year.

CMS has modified the regulation to include a transition period to allow States and governmentally operated non-institutional health care providers sufficient time to develop and implement Medicaid cost documentation and reporting processes consistent with the cost report template issued by CMS (including but not limited to changes in State/provider reporting systems, changes to the Medicaid State plan, changes to time studies, establish periodic review and audit processes, etc.), States will not be required to document and report cost information associated with non-institutional Medicaid services until the State's Medicaid State plan rate year 2009. Actual submission of the State's summary report on the Medicaid cost limit for non-institutional services will not be due to CMS until December 31, 2011, which allows States an opportunity to implement periodic review and audit processes for Medicaid non-institutional costs starting in Medicaid State plan rate year 2009.

Each State is responsible for the proper and efficient administration of its Medicaid program. Expenses incurred for administration of the Medicaid program are eligible for Federal matching funds at the regular 50 percent administrative matching rate.

199C. Comment: One commenter noted the $3.87 billion savings estimate associated with the proposed rule and urged CMS and the Administration to reinvest all savings back into innovations to address the nation's problem of the uninsured and to improve care for current Medicaid individuals.

199R. Response: Spending authority related to any savings generated from the regulation primarily rests with the Congress. Furthermore, State decisions are also a major factor in the financial impact of the regulation and the use of funds. State or local governments may choose to use their funding sources to fund non-Federal share obligations to Medicaid payments historically financed by non-governmentally-operated ''public'' health care providers and may also devote such resources to address the issues described by the commenter.

200C. Comment: One commenter commented specifically on the impact this rule would have on States with large rural populations. In rural areas, the commenter notes, local governments often serve as the only provider to ensure access to needed care, including mental health services and long term care. The payment limits and cost documentation requirements of the rule were identified as particularly challenging for rural local government providers, due to the potential loss of reimbursement and the administrative burden associated with cost documentation.

200R. Response: The Medicaid cost limit permits all governmentally-operated health care providers the opportunity to receive Medicaid revenues up to the full cost of providing services to Medicaid individuals. Furthermore, we do not believe the Medicaid cost limit will impose a significant burden on States or governmentally-operated health care providers.

For non-institutional services provided to Medicaid eligible individuals, a nationally recognized, standard cost report currently does not exist. Because of this, we will be publishing a standardized cost reporting form that should be used to document such services. The purpose of this standardized form is to document in a uniform manner the cost of providing non-institutional services to Medicaid individuals. The period of time to which this cost report applies will be the Medicaid State plan rate year.

CMS has modified the regulation to include a transition period to allow States and governmentally operated non-institutional health care providers sufficient time to develop and implement Medicaid cost documentation and reporting processes consistent with the cost report template issued by CMS (including but not limited to changes in State/provider reporting systems, changes to the Medicaid State plan, changes to time studies, establish periodic review and audit processes, etc.), States will not be required to document and report cost information associated with non-

institutional Medicaid services until the State's Medicaid State plan rate year 2009. Actual submission of the State's summary report on the Medicaid cost limit for non-institutional services will not be due to CMS until December 31, 2011, which allows States an opportunity to implement periodic review and audit processes for Medicaid non-institutional costs starting in Medicaid State plan rate year 2009.

Each State is responsible for the proper and efficient administration of its Medicaid program. Expenses incurred for administration of the Medicaid program are eligible for Federal matching funds at the regular 50 percent administrative matching rate.

201C. Comment: One commenter took exception to the CMS statement in the preamble that it would be beneficial to distribute payments more evenly across all governmental providers because CMS did not provide any analysis or support showing that differential payments to select governmental providers do not serve a rational, favorable purpose, such as promoting the development and maintenance of programs key to the success of the State Medicaid program (even if such services may also be accessed by other individuals).

201R. Response: The Medicaid cost limit permits all governmentally-operated health care providers the opportunity to receive Medicaid revenues up to the full cost of providing services to Medicaid individuals. Because the Medicaid program is jointly funded by Federal, State, and local governments, we do not find it appropriate that units of State or local government would ''profit'' from Federal taxpayer dollars that are intended to match a percentage of the cost of providing services to Medicaid individuals.

K. Effective Date of the Final Regulation

202C. Comment: Many commenters stated that the rule does not have a transition period, arguing that an effective date of September 1, 2007 is too early. Many commenters offered specific suggestions as to the length of a transition period for compliance with the provisions of the proposed rule. The suggested length of transition ranged from a full state fiscal year, to two or three years, to a frequently identified length of ten years following the publication of the final rule. Other commenters suggested a specific date (such as January 1, 2008, September 1, 2008, or January 2009) as an alternative for the rule to become effective. A number of commenters requested ''phase in'' processes for States, local governments, and providers to come into compliance with the provisions of the proposed rule by the effective date.

Different reasons were proffered to argue for transitional periods or phase-in processes. Many commenters noted that the changes proposed in this rule would require action by State legislatures in order to assure compliance. However, these commenters contend that factoring the States' established legislative cycles, there would not be enough time for State legislatures to act to ensure compliance with the rule by the currently proposed effective date of September 1, 2007. In fact, many States have nearly completed or already finalized the budget and all associated Medicaid funding for State fiscal year 2008, but some of the existing funding arrangements or state statutes will need to be modified due to the rule. Some legislatures may not be in session prior to September 1, 2007. Therefore, these commenters have requested a transition period for States, local governments, and providers to adjust to the changes proposed by the rule. Other commenters stated that longstanding payment methodologies and financing arrangements, many of which were previously approved by CMS, would be disrupted by this rule. Based on the administrative and financial changes required, the commenters requested a transition period for States, local governments, and providers to adjust to the proposed rule. Several commenters noted that the proposed rule would require States to submit amendments to their Medicaid State Plan for approval by CMS before they can come into compliance, noting the length of time it takes to develop a State plan amendment, vet it with the public, and receive approval by CMS.

A number of commenters pointed out that States are not obligated to modify their programs based on the provisions of a proposed regulation; therefore, States may not have done anything thus far to comply with the proposed rule. These commenters justified a lack of action based on the possibility that the rule may be altered following the public comment period.

Some commenters opined that establishing appropriate cost reporting mechanisms, as envisioned in the proposed rule, will require months of work, based on the need to define how costs should be allocated and reported and implement any systems changes that will become necessary. Additionally, some of these commenters note that the nature and extent of documentation required to support costs by governmental providers has not been disclosed by CMS. In addition to the cost reporting and State plan changes cited, one commenter noted that government hospitals would need to be removed from the DRG methodology, after which DRG weights would have to be recalibrated and peer groupings excluding these facilities. Therefore, the commenters have asked for a transition period for compliance following the effective date of the rule.

Some commenters observed that the cost limit provision proposed at § 447.206 would become effective on September 1, 2007, while effective dates for other provisions were not specified in the rule. These commenters asked CMS to clarify when all provisions of the proposed rule would be effective.

202R. Response: All provisions of the regulation will be effective 60 days after the publication of the final regulation. Moreover, CMS will require that the States report the universe of governmentally-operated health care providers in each State by submitting a complete list of such health care providers to the Associate Regional Administrator for Medicaid of each State's respective CMS Regional Office within 90-days of the effective date of the regulation. CMS reserves the right to disagree with a State's initial determination of governmental status if we believe the State has not consistently applied the statutory and regulatory criteria to determine the governmental status of a particular health care provider.

With respect to the new cost limit for governmentally-operated health care providers established at § 447.206, a period of transition is warranted in order to ensure that governmentally-operated health care providers document and report their Medicaid costs in a consistent manner. In order to assist States in their obligation to ensure that Medicaid reimbursements to governmentally-operated health care providers do not exceed the individual governmentally-operated health care provider's costs, CMS has developed a general Medicaid cost reporting protocol available on the CMS Web site that specifically addresses the information utilized from each source document and the methods under which costs and revenues will be determined. These protocols have been developed in an effort to address concerns regarding requirements to properly document, audit, and review the costs associated with the provision of Medicaid services in both institutional and non-institutional environments. Timelines for implementation of the cost limit are included in the protocols for both institutional and non-institutional

providers. The timelines have been designed to allow governmentally operated providers and States Medicaid agencies sufficient time to transition into the new requirements of § 447.206.

CMS has developed a general Medicaid Cost Reporting Protocol available on the CMS Web site that specifically addresses the methods under which institutional and non-institutional Medicaid costs will be determined. The protocol was designed to provide States with detailed instructions to determine compliance with Federal requirements.

For purposes of institutional governmentally-operated health care providers, the Medicaid cost limit determination will rely on existing reporting tools used by institutional health care providers. States will not be required to audit financial and cost information provided by individual institutional governmentally-operated health care providers as part of the Medicaid cost limit review. Each of the source documents is subject to reporting and auditing rules specific to the original purpose of that document and independent of the Medicaid cost limit and State review process. The State must render an determination on the cost limit methodology applied to the source documents but will not be required to validate the accuracy of the information and data within the source documents. The Medicaid State plan rate year 2008 will be the first time period subject to the Medicaid cost limit for institutional governmentally-operated health care providers.

For non-institutional services provided to Medicaid eligible individuals, a nationally recognized, standard cost report currently does not exist. Because of this, we will be publishing a standardized cost reporting form that should be used to document such services. The purpose of this standardized form is to document in a uniform manner the cost of providing non-institutional services to Medicaid individuals. The period of time to which this cost report applies will be the Medicaid State plan rate year.

CMS has modified the regulation to include a transition period to allow States and governmentally-operated non-institutional health care providers sufficient time to develop and implement Medicaid cost documentation and reporting processes consistent with the cost report template issued by CMS (including but not limited to changes in State/provider reporting systems, changes to the Medicaid State plan, changes to time studies, establish periodic review and audit processes, etc.), States will not be required to document and report cost information associated with non-institutional Medicaid services until the State's Medicaid State plan rate year 2009. Actual submission of the State's summary report on the Medicaid cost limit for non-institutional services will not be due to CMS until December 31, 2011, which allows States an opportunity to implement periodic review and audit processes for Medicaid non-institutional costs starting in Medicaid State plan rate year 2009.

CMS has modified the regulation to address transitional periods where necessary and detailed cost documentation instructions are available to States as explained above.

203C. Comment: Many commenters expressed concern about the timing of making the changes proposed by this rule in light of larger issues facing our health care system today. Such issues include the risk of terrorist attacks, the possible onslaught of avian flu, and the diversion of ambulances due to facility overcrowding. With these circumstances, the commenters questioned the wisdom in proposing a rule that would withdraw large amounts of Medicaid dollars from institutions that play a significant role in the health care systems of our nations cities.

203R. Response: The Medicaid program is a cooperative Federal-State program established in 1965 for the purpose of providing Federal financial participation (FFP) to States that choose to reimburse certain costs of medical treatment for needy individuals. The provisions of the regulation are consistent with the Medicaid statute.

Medicaid is a vitally important program that serves very vulnerable individuals, and the Federal government remains committed to funding its share of the cost of providing Medicaid services to eligible individuals. We also note that State decisions will be the major factor in the actual financial impact this regulation will have within each State. CMS recognizes that States play a major role in the administration of the Medicaid program and that legal and financial arrangements between health care providers and units of government vary on a case by case basis. Therefore, CMS has developed standardized and impartial regulatory criteria based upon Federal statue that States must apply on a consistent basis to each health care provider within the State to determine whether or not the health care provider is considered a unit of government under the regulation.

Non-governmentally-operated health care providers, including many of the ''public'' safety net health care providers, are not affected by the cost limit provision of the regulation and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements.

Moreover, the regulation reaffirms State Medicaid financing policy requiring that health care providers be allowed to fully retain their Medicaid payments, another provision of which clearly demonstrates the Federal government's intent to protect the nation's public safety net and its ability to continue delivering critical health care services to Medicaid individuals and the uninsured. Any health care providers that become ineligible to participate in the State financing of Medicaid payments following the effective date of the provisions of this regulation can realize greater net revenues if State or local governments choose to utilize their funding sources to fund non-Federal share obligations to Medicaid payments historically financed by non-governmentally-operated ''public'' health care providers.

204C. Comment: Several commenters asked CMS to delay the proposed rule until the impact of the rule can be better identified on both State and national levels.

204R. Response: The provision of the regulation that addresses a unit of government codifies the existing statutory definitions of a unit of government. This codification of existing Federal statute was established in an effort to assist States in identifying the universe of governmentally-operated health care providers that could receive Medicaid revenues up to the full cost of providing services to Medicaid individuals and clarifies which types of health care providers can participate in financing of the non-Federal share of Medicaid payments. CMS has developed standardized and impartial regulatory criteria based upon Federal statue that States must apply on a consistent basis to each health care provider within the State to determine whether or not the health care provider is considered a unit of government under the regulation.

Non-governmentally-operated health care providers, including many of the ''public'' safety net health care providers, are not affected by the cost limit provision of the regulation and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements.

Moreover, one provision of the regulation reaffirms State Medicaid

financing policy requiring that health care providers be allowed to fully retain their Medicaid payments, another provision of which clearly demonstrates the Federal government's intent to protect the nation's public safety net and its ability to continue delivering critical health care services to Medicaid individuals and the uninsured. Any health care providers that become ineligible to participate in the State financing of Medicaid payments following the effective date of the provisions of this regulation can realize greater net revenues if State or local governments choose to utilize their funding sources to fund non-Federal share obligations to Medicaid payments historically financed by non-governmentally-operated ''public'' health care providers.

For the above reasons, we do not believe it is appropriate to delay the regulation.

205C. Comment: Multiple commenters asked that if the proposed rule is to become effective, that it should only be effective prospectively, not retroactively.

205R. Response: The provisions of this regulation will be effective 60 days after publication of the final regulation. While the provisions of the regulation will not be applied retroactively, total Medicaid revenues must be reconciled to actual Medicaid costs for purposes of compliance with the Medicaid cost limit. CMS has developed a general Medicaid Cost Reporting Protocol available on the CMS Web site that specifically addresses the methods under which institutional and non-institutional Medicaid costs and revenues will be determined. The protocol was designed to provide States with detailed instructions to determine compliance with Federal requirements.

206C. Comment: Multiple commenters expressed the belief that an effective date of September 1, 2007 would be impossible to achieve when it is not known in advance who qualifies as a unit of government under the proposed rule.

206R. Response: All provisions of the regulation will be effective 60 days after the publication of the final regulation. Moreover, CMS will require that the States report the universe of governmentally-operated health care providers in each State by submitting a complete list of such health care providers to the Associate Regional Administrator for Medicaid of each State's respective CMS Regional Office within 90-days of the effective date of the regulation.

207C. Comment: A number of commenters stated that to the extent that CMS contends that the current regulatory change is effective at any time prior to the finalization of the formal rulemaking process, it is in violation of not only the Administrative Procedures Act but also the Medicaid Voluntary Contribution and Provider-Specific Tax Amendments of 1991, which contained an uncodified provision to prevent the Secretary from issuing any interim final regulation to change the treatment of public funds as a source of the non-Federal share (see 5 U.S.C. 553).

207R. Response: Section 5(c) of the Medicaid Voluntary Contribution and Provider-Specific Tax Amendments of 1991, Public Law 102–234, required the Secretary to ''consult with the State before issuing any regulations under this Act.'' CMS interprets this provision as a check on the authorization to use interim final rulemaking procedures in section 5(a). We thus read the reference to ''any regulations'' to refer to the regulations specifically authorized under section 5(a) to be issued ''on an interim final or other basis'' to initially implement the Act. We do not read the condition as a permanent limitation on Secretarial rulemaking authority. We believe the condition was fully satisfied by the process the Secretary undertook when the regulations implementing that Act were issued in 1992 and 1993. Even if the condition were read to extend in perpetuity, however, we believe it has been met with respect to these regulations. Over the years, in the course of reviewing State plan amendments, CMS is in constant dialogue with States over issues relating to the financing of the Medicaid program. The general principles contained in this regulation have been explored with States over the years. Moreover, this Administration has announced its intentions with respect to this regulation in the President's Budget, and we have undertaken full notice and comment rulemaking procedures. In this process, we have received and considered numerous comments from States and other interested parties.

L. Miscellaneous Comments

1. Tribal Comments

208C. Comment: Several commenters observed that under the proposed rule, Indian Tribes would only be able to participate in the non-Federal share if it has ''generally applicable taxing authority.'' The commenters noted that the Indian tax law is complex, fraught with exceptions, and often the subject of litigation between Indian Tribes and States, but the proposed rule would require each State to analyze specific aspects of taxing structures of every tribe within the State. Therefore, it was noted that the taxing authority requirement to determine that a tribe is a unit of government will negatively affect the willingness of States to enter into cost sharing agreements with Indian Tribes, especially since an error in the determination could potentially have a negative financial consequence for the State.

In a related comment, one commenter expressed an opinion that the criteria of the proposed rule to require Indian Tribes to have generally applicable taxing authority to be considered a unit of government or a governmental health provider contradicts over 100 years of treaties, statutes, executive orders, and court decisions recognizing and cementing the unique government-to-government relationship the United States has with Tribal governments. The commenter noted that some tribal governments have taxing authority but do not exercise their taxing authority. The commenter indicated that since many tribal organizations do not have taxing authority, they would not qualify as a unit of government under the proposed rule. The commenter therefore believed that this criteria for purposes of the Medicaid program is both morally wrong and possibly illegal.

In light of the above, commenters suggested amending proposed § 433.50(a)(1)(i) to specifically address this issue.

208R. Response: CMS has modified the regulation at § 433.50(a)(1)(i) to include Indian tribes as units of government without regard to taxing authority, in light of their unique status and government-to-government relationship to the Federal government..

209C. Comment: A number of commenters stated that the proposed rule appeared to reverse the policy provided in the October 18, 2005 and June 9, 2006 State Medicaid Director (SMD) letters. The commenters are concerned that the proposed rule appears to further restrict Tribes and tribal organizations from participation in financing the non-Federal share by requiring the entity to have general applicable taxing authority.

209R. Response: The provisions of the regulation were not intended to reverse policies articulated in the October 18, 2005 and June 9, 2006 SMD letters concerning the ability of tribes and tribal organizations to use certified public expenditures as a method of participating in the financing of the non-Federal share of Medicaid administrative expenses.

CMS has modified the regulation at § 433.50(a)(1)(i) to address Indian tribes as units of government irrespective of their taxing authority.

In addition, CMS is not requiring States to complete the ''Tool to Evaluate the Governmental Status of Health care Providers'' form for each Indian tribe and tribal organization within the State, because the unique criteria for determining the governmental status of tribes and tribal organizations makes the tool inapplicable to these entities. However, CMS does require each State to specify the qualifying tribes and tribal organizations (per the criteria at § 433.50) in the list of all governmentally-operated health care providers that will be submitted to the CMS Regional Office within 90-days of the effective date of this regulation. Although tribal facilities are exempt from the Medicaid cost limit, the inclusion of tribes and tribal organizations in this list will clarify which entities have been determined by the State as eligible to participate in financing the non-Federal share of Medicaid payments.

210C. Comment: Several commenters asserted that the proposed rule should include language to indicate that other funds of the Indian Tribe, including funds transferred to the Tribe under a contract or compact pursuant to the Indian Self-Determination and Education Assistance Act, Public Law 93–638, as amended, should be permissible sources of funding without regard to whether they were derived from general applicable taxing authority. In addition, the commenters requested the inclusion of language in the proposed rule to make clear that irrespective of the form of Medicaid reimbursement, the Tribe or Tribal organization will not be disqualified from participating in the non-Federal share. The commenters specifically suggested amending proposed § 433.50(a)(1)(ii) by adding a new section (C) and provided suggested language.

210R. Response: CMS has modified the regulation at § 433.50(a)(1)(i) to address Indian tribes as units of government regardless of their taxing authority.

We note that currently § 433.51(c) already indicates that ''Federal funds authorized by Federal law to be used to match other Federal funds'' are permissible sources of financing the non-Federal share of Medicaid expenditures. We further recognize that Federally-granted ISDEAA funds continue to be permissible sources of funding for the non-Federal share of Medicaid expenses.

211C. Comment: One commenter opined that CMS ''purposefully and willfully misdirected the States and Indian Tribes'' by consulting with tribes relative to the October 18, 2005 and the June 9, 2006 SMD letters while failing to consult with tribes with respect to provisions of the proposed rule that seem to contradict the two SMD letters. The commenter questioned the timing of the tribal consultation in relation to the development of these regulations, and the commenter requested the outcome of such consultations. Further, the commenter questioned if CMS violated its own tribal consultation policy by not consulting with the Tribe or the Tribal Technical Advisory Group (TTAG) until after a month after these proposed regulations were published.

211R. Response: CMS has worked collaboratively with tribes and States to address unique tribal health care issues and will continue these efforts in the future. The provisions of the regulation were not intended to reverse policies articulated in the October 18, 2005 and June 9, 2006 SMD letters concerning the ability of tribes and tribal organizations to use certified public expenditures as a method of participating in the financing of the non-Federal share of Medicaid administrative expenses. CMS has modified the regulation at § 433.50(a)(1)(i) to address Indian tribes as units of government irrespective of their taxing authority.

212C. Comment: One observation was made that the proposed regulations would appear to negate some of the benefits that would be gained through the recently proposed bill (SB 578) protecting the Medicaid to Schools program.

212R. Response: The requirements proposed in §§ 433, 447, and 457 are consistent with the Medicaid statute.

2. Section 1115 Demonstrations/ Managed Care Comments

213C. Comment: Numerous commenters were confused and requested further clarification regarding the applicability of the proposed provisions of the regulation to section 1115 demonstration waivers. The commenters were particularly confused since the preamble to the proposed provisions specifically mentions that the regulations will apply to demonstration waivers, but on several occasions CMS has provided assurances to individual States that the proposed provisions of the regulation would not affect their current 1115 waiver program. The commenters also mentioned that not only are these assurances inconsistent with the preamble language, they are also inconsistent with the terms and conditions of the waivers, which specify that the waiver program will need to be modified to conform to changes in applicable law and regulations.

213R. Response: All Medicaid payments made under Medicaid waiver and demonstration authorities are subject to all provisions of this regulation. The impact on individual waiver programs will have to be determined on a waiver by waiver basis to ascertain what, if any, changes will need to be made to address the final provisions of the regulation. Under recent 1115 waiver demonstration approvals and renewals, CMS provided States with guidance and parameters consistent with the provisions of the regulation. In fact, we have demonstrated through recent 1115 demonstration approvals that we have been able to successfully work with States to design programs that meet both Federal Medicaid statutory financing requirements as well as the States' need to develop programs to effectively deliver health care to safety net populations.

214C. Comment: Multiple commenters stipulated that if the proposed provisions of the regulation are finalized as is, they would be extremely disruptive and harmful to existing waiver programs. These commenters cited specific concerns such as, use of CPEs by public entities that may not satisfy restrictive definitions of the proposed provisions of the regulation, utilization of payment methodologies that are not limited to cost and reliance on sources other than State or local taxes to provide the non-Federal share of expenditures. The commenters were also concerned that impacted waivers in States would not be able to obtain renewal of their program, without complying with the proposed provisions of the regulation, which could undermine the entire rationale for the waiver program. The commenters opined that these demonstration waivers are an important part of the Medicaid program and imposing these restrictive provisions would only stifle initiative, innovation and improvements to the delivery of health care. The commenters strongly recommended that if adopted, 1115 demonstration programs should be expressly exempted for as long as the program remains in effect, including through subsequent renewal periods. A few commenters stated that if their special funding pool under their 1115 waiver is exempt, then their DSH program and supplemental physician payments should be as well.

Other commenters requested that CMS clarify that the provisions of the

regulation would not result in reduced funding below the levels that were already agreed upon in the terms and conditions of waivers. The commenters also urged CMS to apply criteria used to approve waivers and establish their terms and conditions in a consistent and transparent manner across all States.

214R. Response: We agree that demonstration programs are an important part of the Medicaid program, however, we disagree that the provisions of the regulation will stifle innovation and improvement in the delivery of health care. The provisions of the regulation reaffirm State Medicaid financing policy and clearly demonstrate the Federal government's intent to protect the nation's health care safety net to continue to delivery critical health care services to Medicaid individuals and the uninsured. The impact on individual waiver programs will have to be determined on a waiver by waiver basis to ascertain what, if any, changes will need to be made to address the provisions of the regulation once finalized. Our intent is not to prevent renewal of any demonstration program as long as it is consistent with Federal Medicaid statutory requirements governing the financing of the Medicaid program. In fact, we have demonstrated through recent 1115 demonstration approvals that we have been able to successfully work with States to design programs that meet both Federal Medicaid statutory financing requirements as well as the States' need to develop programs to effectively deliver health care to safety net populations. Therefore, we disagree that 1115 demonstration programs be exempted. There are also existing established waiver approval criteria that are used to promote consistency and transparency.

215C. Comment: Numerous commenters requested CMS to explicitly state in the final provisions of the regulation that the funding for specific State 1115 waivers would not be reduced or eliminated as a result of the provisions within the regulation. Several commenters discussed Florida's establishment, after complex and lengthy negotiations with CMS, of its Low Income Pool authorized through the authority under section 1115(a)(2) of the Act. Other commenters referenced California's Hospital Waiver that includes a Safety Net Care Pool designed to provide Federal match to State, public hospitals and other public entities' expenditures on services to the uninsured. These commenters mentioned that under the authority of section 1115(a)(2) of the Act, CMS allows these expenditures to be matched even though expenditures for the uninsured would not normally be eligible for Federal matching under Medicaid. The commenters are concerned that the provisions of the regulation would lower payments to hospitals under the Hospital waiver, resulting in reduced access to services for vulnerable populations, including children. At a minimum these commenters requested CMS specifically address their waiver programs, but overall recommend that the entire regulation be withdrawn.

215R. Response: We have already articulated clearly to the cited States that based upon the premises and design of their demonstration programs, they should not be impacted by the final regulation's provisions. For Florida, while we are still working with the State to define expenditures that can be made through the Low Income Pool, approved expenditures will be eligible for Medicaid matching consistent with the authority under section 1115(a)(2) of the Act for the Secretary to provide federal matching for costs not otherwise matchable under Medicaid. In the case of California, the new MediCal reimbursement system pays certain government providers 100 percent of costs incurred for services furnished to Medicaid individuals and up to 100 percent of their DSH eligible costs (which would include costs of services provided to the uninsured) subject to allotment limitations. One of the fundamental tenets of the demonstration and their reimbursement and funding methodologies is the payment of providers up to their full cost of providing hospital services to Medicaid individuals and to uninsured individuals. Under the demonstration, the uninsured costs are considered eligible under Medicaid and would be part of each government hospital's Medicaid cost base for purposes of the regulation. The Medicaid financing reforms adopted under California's 1115 demonstration are largely consistent with policies addressed in the provisions of the regulation therefore, to the extent these reforms continue to be met, it is unlikely that the demonstration's budget neutrality agreement would be adversely affected by the regulation. We do not believe that any additional statements are needed in the final regulation.

216C. Comment: One commenter specified that it was unfair to force them to eliminate payments above cost when other States have been afforded the opportunity to retain such payments and funds through the waiver process. The commenter referenced the fact that CMS has allowed several States to receive above cost payments for governmental providers and use those funds, through a demonstration waiver, for low-income or safety net care pools in order to facilitate payments to health care providers who serve uninsured or low-income individuals.

216R. Response: Each State with the type of approved 1115 demonstration program referenced by the commenter has demonstrated permissible sources for the non-Federal share of Medicaid payments. One of the fundamental tenets of this type of demonstration and reimbursement and funding methodologies is the payment of providers up to their full cost of providing hospital services to Medicaid individuals and to uninsured individuals. Under such a demonstration, the uninsured costs are considered eligible under Medicaid and would be part of each government hospital's Medicaid cost base for purposes of the regulation.

217C. Comment: A few commenters asked that CMS specify that adjustments to any budget neutrality calculations will not be necessary as a result of the proposed rule's provisions. A few commenters mentioned that the terms and conditions within 1115 demonstration programs specifically require that CMS must adjust the budget neutrality cap to take into account reduced spending that would be anticipated under new regulations. The commenters asked if CMS would enforce this requirement and renegotiate budget neutrality agreements. Another commenter requested that CMS specifically explain how the proposed rule will affect States' existing waiver budget neutrality calculations and if States have to recalculate, which States will be adversely affected.

217R. Response: Budget neutrality, except for funds associated with DSH conversions, is based on payments for medical services provided to Medicaid eligible individuals. These payments, including supplemental payments, are paid to health care providers based on services delivered to Medicaid eligible individuals. The provisions of this regulation would affect spending under the State plan only to the extent that payments associated with individuals receiving services from governmentally-operated health care providers are limited. The regulation would not limit the States' ability to make Medicaid payments, including supplemental payments, but would limit the amount of FFP available to States making Medicaid payments to governmentally-operated health care providers for any Medicaid payment that was above that provider's cost.

Adjustments to budget neutrality are made generally to address the effects on FFP of Federal Medicaid changes (limits or expansions) to benefits, coverage or eligibility under a Medicaid State Plan. For instance, if there was a change in federal law that required a new Medicaid service to be offered to all Medicaid eligible individuals, a State with a comprehensive section 1115 demonstration may request to open their budget neutrality agreements to include the cost of this new service within the agreement because they are required to provide it under the demonstration. This regulation only affects FFP available for Medicaid payments to select providers and not the services and eligibility categories that defined the budget neutrality calculation. Therefore, CMS would not consider this regulation a change that would require the recalculation of existing budget neutrality agreements.

218C. Comment: A few commenters stated that the current UPL policy discourages the expansion of Medicaid managed care. The commenters noted under current regulations, States may only count the services utilized by Medicaid individuals that are paid on a fee-for-service basis. Services provided to Medicaid individuals enrolled in managed care on a capitated contracting basis are not counted towards the calculation of the UPL. Therefore, as managed care enrollment increases, the UPL decreases and the opportunity to obtain supplemental payments for safety net providers is drastically reduced. The commenters argued that because of this flawed methodology, many types of providers and local governments oppose managed care expansions. The commenters expressed their belief that expanded Medicaid managed care can slow the growth of Medicaid costs, lead to more efficient service delivery and promote high quality integrated systems of care. One commenter stated this policy prevents States from moving from a costly, unmanaged system of care to a model that provides coordinated care for individuals. Another commenter cited a recent Lewin Group report that highlighted the difficulties States face and how the current UPL policy detracts from savings that could be achieved through more efficient and effective delivery systems. The commenters recommended that managed care days be included in the calculation of UPLs. The commenters opined that this will prevent large decreases in payments to safety net providers, while also resulting in significant savings to the Federal and State governments. They also indicated that this would be consistent with the treatment of managed care days in DSH, as the formula used to calculate the maximum allowable DSH payment to hospitals does not distinguish between fee-for-service and managed care days.

218R. Response: We disagree with the commenters' suggestions, since this regulation is actually designed to protect health care providers, including safety net providers. Under the provisions of the regulation, governmentally-operated health care providers are assured the opportunity to receive full cost reimbursement for serving Medicaid individuals. Non-governmentally operated health care providers, including many of the ''public'' safety net hospitals, are not affected by the cost limit provision of the regulation and therefore, may continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements. While we understand the circumstance raised by the commenters, as stated above, the provisions of this regulation would allow governmentally-operated health care providers to receive the full cost of providing services to Medicaid individuals and non-governmentally-operated health care providers would still be able to receive Medicaid payments above cost that could help offset any managed care shortfalls perceived by providers.

Governmentally-operated health care hospitals that realize a Medicaid managed care ''shortfall'' may continue to receive Medicaid DSH payments to satisfy such unreimbursed Medicaid costs. The ''UPL'' referenced by the commenters is a ceiling on Medicaid fee-for-service reimbursement systems and is calculated based on the Medicaid populations covered under such fee-for-service reimbursement system. The inclusion of managed care days in a fee-for-service payment limit demonstration is inconsistent with the purpose of such a demonstration.

The regulations governing payment under the fee for service program are separate from the authority located in § 438 for rates paid under capitated arrangements. Federal regulation requires that rates established for services under capitation arrangements be considered as payment in full. Further, Medicaid capitation payments are rooted in actuarial principles and practices and are appropriate for the individuals covered, and the services to be furnished under the contract. All of these provisions taken together should ensure that every Medicaid provider is paid appropriately for the services they deliver and has the ability to ensure continued access to services delivered on either a fee-for-service or capitated basis.

219C. Comment: A couple of commenters expressed concern regarding the proposed unit of government definition and its impact on local managed care organizations (MCOs). The commenters articulated that because many State and local governments were instrumental in the development, launch and operation of local MCOs, the local administrators of these plans are often considered public entities under State statute. The commenters are concerned that these MCOs will fall under the new unit of government definition which would create unequal treatment between commercial and public MCOs. The commenters argued that this may create incentives to qualify quasi-governmental MCOs as units of government in order to allow eligible IGTs or CPEs to flow from these entities, while commercial MCOs would be left to compete under inequitable rules of competition. The commenters requested that CMS strictly enforce the unit of government definition as they apply to MCOs and should clarify that States may not consider an MCO's public status in procurement decisions and auto-assignment algorithms.

219R. Response: The Federal Medicaid statute does not include a term or discussion that references a ''public'' health care provider for purposes of State Medicaid financing. The Federal Medicaid statute at section 1903(w) places severe statutory restriction on States' receipt of funds from health care providers to fund Medicaid payments. This section of the statute includes an exception to the general prohibition on the receipt of voluntary contributions from health care providers by allowing units of government, including governmentally-operated health care providers, to participate in the certified public expenditure process. The notion that quasi-governmental MCOs can ''qualify'' as a unit of government is misleading since any entity that can be determined to be a unit of government must meet the strict Federal statutory and regulatory criteria.

If a managed care organization were determined to be governmental, we find it illogical that such an entity would utilize CPEs for the financing of its capitation payments. Such participation would not appear to create any benefit over private MCOs as suggested by the commenters. This seems to be counter intuitive to the very nature of managed care. First, a CPE would require reconciliation to actual costs of

delivering health care services to Medicaid individuals and would remove any possibilities of profit. Second, it is not clear how an entity's governmental status will create inequitable rules of competition considering the use of a CPE requires such governmental entity to expend funds to receive Federal matching funds and the MCO effectively would only receive the Federal share of the capitation payments.

220C. Comment: One commenter stated that the proposed cost limit appeared to apply to payments made by Medicaid MCOs to public providers. The commenter stipulated that the application of a retrospective cost limit to managed care services will preclude providers from negotiating for and receiving capitation payments, and would contradict the principles of managed care. The commenter requested that CMS clarify that these payments are excluded from the proposed cost limit.

A few commenters requested that CMS clarify the proposed rule's applicability to MCOs. The commenters specifically inquired as to how the cost limit applies to government providers participating in an MCO network. Other commenters stated that the proposed rule be clarified to indicate that MCOs, including prepaid inpatient health plans, are not subject to the proposed rule's cost limitation requirements with respect to both a State's payment to a MCO and to a MCO's payment to governmental providers. The commenters recommended that this be specifically articulated within the regulation text itself at §§ 447.206, 447.272(b)(4) and 447.321(b)(4).

One commenter stated that Pre-Paid Inpatient Health Plans (PIHPs) bear risk and must retain the ability to have risk reserves and carry forward funds for services and supports to Medicaid individuals that are specifically approved as part of reinvestment planning. Therefore, limiting these entities to actual cost will cause harm to the Medicaid individuals served.

220R. Response: We partially agree with the commenters that additional clarity is necessary regarding the applicability of the Medicaid cost limit and have modified the regulation to include an exception in § 447.206(b) for MCOs, PIHPs and PAHPs. Ultimately, payments to MCOs, PIHPs and PAHPs are rooted in actuarial principles and practices and are appropriate for the individuals covered and the services furnished under the contract, under § 438.6(c). An MCO, PIHP or PAHP's Medicaid payments to a governmentally-operated health care provider would be subject to the Medicaid cost limit for that governmentally-operated health care provider. The Medicaid payment received by the governmentally-operated health care provider from an MCO, PIHP or PAHP would be treated as a Medicaid revenue of the governmentally-operated health care provider and would have to be reconciled against the governmentally-operated health care provider's actual costs of delivering health care services to all Medicaid individuals.

221C. Comment: A few commenters stated that if the proposed rule is not withdrawn States should be given ample time to make necessary changes. Further, CMS should clarify that the changes will be prospective and not retroactive. The commenters were most concerned about the timing as it relates to States operating CMS approved section 1115 waivers. The commenters noted that the terms and conditions of many of these waivers would have to be changed and, if applicable, the use of IGTs and/or CPEs and the overall amount of spending allowed under the waiver. Other commenters noted that changes to government physician rates would need to occur after cost report data has been established for such services, but actuaries would need time to reestablish payment ranges based on cost because these rates currently include a primary care case management capitation component. Finally, States would need time to amend 1115 demonstrations for certain payments provided to government operated providers that may be in excess of cost.

221R. Response: The provisions within this regulation will not be applied retroactively. The regulation is effective 60 days after publication in the **Federal Register**.

222C. Comment: A couple of commenters requested that CMS clarify whether it will allow other States to adopt similar waivers which may incorporate savings realized from the proposed rule's cost limit into their own safety net care pools or coverage expansion initiatives. The commenters also requested that if CMS does not plan to allow other States to make sure of cost limit savings, what would be its legal basis for its decision.

222R. Response: The opportunity for future demonstration programs is always available to States. Any such proposal must, in part, demonstrate permissible sources of the non-Federal share funding and compliance with all other Federal statutory and regulatory provisions governing Medicaid payments. Section 1115 demonstrations were only approved after each State documented an accountable and transparent financing and health care delivery system. Our legal basis for determining the allowability of any demonstration program is based in any such demonstration's compliance with all applicable Federal statutory and regulatory provisions.

223C. Comment: Numerous commenters requested that the proposed cost limit be revised to include, as an allowable cost, an actuarially sound provision for risk reserves when a unit of government has entered into a risk-based contract with an MCO or PIHP. The commenters stipulated that the proposed cost limit requirements would render all sub-capitation arrangements with counties financially unsustainable since there would be no mechanism for building a risk reserve and managing the mismatch of revenue and expense across fiscal years. The commenters noted that this would have particular impact for health plans operating in small rural areas. The commenters expressed their belief that the proposed rule restricts units of government from entering into Medicaid risk-based contracts and creating a disadvantage for local governments that would desire to provide services where the market is not likely to do so.

223R. Response: We do not believe that the suggested changes are necessary since the cost limit provisions do not apply to MCOs, PIHPs or PAHPs.

224C. Comment: Several commenters stated that CMS should allow States to make direct payments to governmental providers for unreimbursed costs of serving Medicaid managed care enrollees. Current Medicaid managed care regulations prohibit States from making direct payments to providers for services available under a contract with a managed care organization and Prepaid Inpatient Health Plan or a Prepaid Ambulatory Health Plan. There is an exception to this prohibition on direct provider payments for payments for graduate medical education, provided capitation rates have been adjusted accordingly. Since this proposed rule will result in extreme funding cuts, CMS should reconsider the scope of the exception to the direct payment provision. If reimbursement to governmental providers is going to be restricted to cost, it should include costs for all Medicaid individuals, not just those in the declining fee-for-service population. Other commenters stated that because these payments would now be based on costs, there would not be the danger of ''excessive payments'' that has concerned CMS in the past. The commenters specifically requested that

CMS amend §§ 438.6(c)(5)(v) and 438.60 to allow for direct payments to governmental providers for unreimbursed costs of Medicaid managed care patients.

224R. Response: Under the regulations governing payments under risk contracts in § 438.6(c), States are expected to make actuarially sound payments to MCOs, PIPHs, and PAHPs that include amounts for all services covered under the contract. We do not believe there should be a need for payments directly from the States to providers who are delivering their services to Medicaid MCO enrollees. Sections 438.6(c)(5)(v) and 438.60 were designed to prevent duplicate and inappropriate supplemental payments for services for which the State had contracted with an MCO to provide. Under a managed care capitation payment systems, a State has in effect already paid for services that are included in an MCO's contract, and does not have an obligation to pay for them a second time.

225C. Comment: Several commenters requested that CMS clarify that the cost limit based on the ''cost of providing covered Medicaid services to eligible Medicaid recipients'' does not exclude costs for payments authorized under Section 1115 demonstration programs that expressly allow payment for individuals or services not covered under the State Medicaid plan. The commenters were concerned that proposed § 447.206(c)(1) specifies that ''all health care providers that are operated by units of government are limited to reimbursement not in excess of the individual provider's cost of providing covered Medicaid services to eligible Medicaid recipients.'' The commenters believed this would preclude any Medicaid reimbursement to governmental providers for costs of care for patients who are not eligible Medicaid individuals or for services that are not covered under the State Medicaid plan.

The commenters questioned whether it is CMS' intent to either (1) apply the cost limit only to fee-for-service payments by the state agency for services provided to Medicaid individuals while relying on separate statutory or waiver-based authority to impose cost limits or demonstration program expenditures, or (2) to apply the cost limit more broadly than the language of the proposed rule would suggest. The commenters stated that preamble guidance regarding the ongoing validity of expenditure authority granted through existing demonstration projects would help reduce confusion about the intended scope. CMS should also clarify that the limitation to cost of Medicaid services for Medicaid individuals is not intended to limit CMS approved payments under demonstration programs that expressly allow payment for individuals or services not covered under the State Medicaid plan.

225R. Response: Costs and populations that are otherwise not considered eligible for Medicaid matching purposes can be determined allowable under a section 1115 demonstration through the authority under section 1115(a)(2) of the Act which allows the Secretary to provide federal matching for costs not otherwise matchable under Medicaid. Such expenditures are eligible for Medicaid matching and would be recognized under the Medicaid cost limit provisions.

3. Other Miscellaneous Comments

226C. Comment: One commenter opined that the provisions of the regulation would be a barrier to the provision of federal Medicaid funding for Medicaid services delivered as part of an Individual Education Plan or Individualized Family Service Plan under IDEA.

226R. Response: The Individuals with Disabilities Education Act (IDEA) is a law ensuring services to children with disabilities. IDEA governs how States and public agencies provide early intervention, special education and related services to eligible children with disabilities. Section 1903(c) of the Act permits Medicaid reimbursement for Medicaid covered services provided to Medicaid eligible children under IDEA. The regulation does not require States to dismantle any of the existing Medicaid reimbursement rate methodologies they are currently using to reimburse providers of IDEA services.

The provision of the regulation that addresses a unit of government codifies the existing statutory definitions of a unit of government. This codification of existing Federal statute was established in an effort to assist States in identifying the universe of governmentally-operated health care providers that could receive Medicaid revenues up to the full cost of providing services to Medicaid individuals and clarifies which types of health care providers can participate in financing of the non-Federal share of Medicaid payments.

227C. Comment: One commenter stated that the No Child Left Behind Act increased paperwork requirements for schools and that the provisions of the regulation would add to the extensive paperwork burden already in place.

227R. Response: The paperwork requirements of the No Child Left Behind Act are outside of the purview of CMS and the Medicaid program. With respect to the burden of the provisions of this regulation, we have modified the regulation to include a transition period to allow States and governmentally-operated non-institutional health care providers, such as schools, sufficient time to develop and implement Medicaid cost documentation and reporting processes. States will not be required to document and report cost information associated with non-institutional services such as those provided in schools until the State's Medicaid State plan rate year 2009.

228C. Comment: Some commenters were severely disturbed that CMS is limiting the extent to which Medicaid funds can be used to pay for uninsured care. The commenters disagreed with CMS and stated that Congress has never precluded providers from using their Medicaid revenues to care for the uninsured. One commenter argued that Congress has expressly provided for this through the passage of laws, including the Medicaid disproportionate share program (DSH) and the Benefits Improvement Act of 2000 (BIPA). The commenter noted that section 701(d) of BIPA provided direct funds to a governmentally-operated hospital with a 65 percent low income utilization rate that was not receiving DSH payments.

Another commenter requested that CMS include specific language in the regulatory text at §§ 447.207 and 447.272 to exempt payments authorized by sections 701(d) and 705 of BIPA. These payments allow the State to contribute to its entire safety net for needy individuals.

228R. Response: The fact that Congress has specifically provided for funding to pay for uninsured care in certain specified circumstances supports the general rule that, absent such specific authorization, Medicaid payments should be limited to supporting covered services for eligible individuals. We agree that the regulation should reference the specific statutory exceptions, and we are revising the regulation accordingly.

229C. Comment: A few commenters expressed concern that the new limitations on allowable services under the rehabilitation option would be harmful to persons with mental retardation and currently receiving health-related specialty services that allow them to participate meaningfully and in a more mainstreamed manner in the public education system.

229R. Response: The commenters' concerns are outside the scope of this

regulation. The regulation does not contemplate limitations on services under the rehabilitation option.

230C. Comment: A couple of commenters questioned how this proposed rule interacts and impacts Pay for Performance (P4P) models. The commenters indicated that States have been encouraged by CMS to consider innovative payment strategies to pay providers a higher rate for adhering to certain quality indicators to achieve better individual health outcomes. The commenters stated that a governmentally operated provider will not be incentivized to meet quality goals or performance standards if they will be reimbursed according to cost.

Further, the commenters questioned how any State can move forward with reimbursement policies incorporating quality measures if they won't apply to all providers of a service.

230R. Response: We do not believe the provisions of this regulation will have any negative impact on Pay for Performance (P4P) models. This regulation does not preclude States from using innovative payment strategies to pay providers a higher rate for adhering to certain quality indicators to achieve better individual health outcomes. The method by which a State may choose to accomplish its quality-based purchasing program can vary greatly because of the variety of approaches available to a State to administer its Medicaid program. States maintain flexibility, within established Federal statute and regulations, to decide on medically necessary services that will be covered and rates that will be paid to providers.

Under this regulation, governmentally-operated health care providers are assured the opportunity to receive full reimbursement for the cost of serving Medicaid individuals and except when a CPE is utilized as the non-Federal share of Medicaid payments, a cost reimbursement methodology within the Medicaid State plan is not required. States have the flexibility to pay the rate they choose as long as it does not result in Medicaid payments being greater than Medicaid costs in the governmentally-operated health care provider. Non-governmentally-operated health care providers may continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements.

231C. Comment: A couple of commenters expressed their disappointment that CMS chose to issue this proposed rule so soon after passage and in the midst of implementation of the Deficit Reduction Act of 2005 (DRA). The commenters stated that having to implement this rule on top of the burdens placed on States as a result of the DRA (that is, documenting citizenship and identity), imposes extreme financial burden. The commenters stipulated that such a cost shift to States will hamper efforts to expand access to care to all children qualifying for Medicaid and SCHIP and to reach those children not currently eligible. The commenters recommended that CMS allow States to implement the DRA changes before making such a drastic change to Medicaid financing policies and practices.

231R. Response: We do not believe the burden associated with the provisions of the regulation will impede States' ability to address any of the provisions within the DRA. Many of the provisions within this regulation codify existing Federal Medicaid law and do not represent policy change. Medicaid is a shared responsibility between Federal and State government. States are responsible for ensuring that their administration of their Medicaid program is in compliance with all Federal statutory and regulatory requirements.

232C. Comment: One commenter noted that in response to the DRA, CMS outlined several new flexibilities available to States to help people served by Medicaid programs maintain access to affordable health care and allow States to use innovative approaches to providing health insurance and long-term care services. The commenter indicated that one such initiative is ''Roadmaps to Medicaid Reform''. The commenter stated that the proposed rule would erode the intent of the DRA and CMS'' on-going Medicaid reform efforts. The commenter strongly urged CMS to consider the effect this proposed rule will have on initiatives and the conflicting message sent to the States that have begun taking advantage of these reform measures.

Another commenter stated that the proposed rule could derail their efforts to cover more uninsured through their State's health care improvement act, which follows the President's proposal of shifting Federal funding to help the uninsured buy private insurance and take ownership of their healthcare.

232R. Response: We believe that nothing in this regulation prevents a State from implementing any flexibilities or innovations within their Medicaid programs. This regulation is merely designed to ensure the fiscal integrity of the Medicaid program.

States maintain flexibility, within established Federal statute and regulations, to decide on medically necessary services that will be covered, populations that will be covered and rates that will be paid to health care providers. We will continue to work with States to determine the proper methods to implement such initiatives. There continue to be a variety of mechanisms States can use to achieve its specific goals for its Medicaid program including, but not limited to State plan changes, a Medicaid 1115 demonstration project application or amendment, or through a section 1915(b) or 1915(c) waiver.

233C. Comment: Several commenters strongly opposed the President's fiscal year 2008 budget proposal to eliminate Medicaid graduate medical education (GME) funding. The commenters first questioned whether the Administration could even implement such a proposal without explicit statutory direction and if so, they presume CMS would purse this change through the notice of proposed rulemaking process. Other commenters urged CMS not to move forward with any proposal that would implement the President's budget proposal.

233R. Response: Any changes related to Medicaid reimbursement for GME costs contained in the President's fiscal year 2008 would be published in the **Federal Register** and afford interested parties the opportunity to provide comment.

234C. Comment: One commenter requested that CMS instruct States that outpatient drugs provided by governmentally-operated health care providers are excluded from Medicaid rebates under section 1927(j)(2) of the Act. The commenter believes the proposed rule will exclude outpatient drug utilization by providers from the Medicaid rebate program because the government will get the full benefit of any price reductions these providers obtain. The commenter further stipulated that under current Medicaid rebate law, hospitals that bill Medicaid no more than the hospitals' purchasing costs for covered outpatient drugs are not subject to the Medicaid rebate program. Because governmentally operated hospitals will receive no more than the purchasing costs for covered outpatient prescription drugs, they must be excluded from the Medicaid rebate program. The commenter reasoned that the Medicaid program will enjoy the benefit of whatever price reductions the hospitals negotiate with manufacturers.

234R. Response: The treatment of outpatient drugs furnished by governmentally-operated health care providers for purposes of drug rebate is outside of the scope of this regulation.

235C. Comment: One commenter suggested where fee-for-service payments to governmental providers constitutes a small percentage of a State's total medical assistance (the commenter suggested less than 5 percent) due to either widespread use of managed care or lack of governmental providers, the entire Medicaid program should be exempt from the proposed rule provisions. The commenter recommended including this exemption in the following proposed regulatory provisions §§ 433.51(b)(3), 447.206, 447.272 and 447.321.

235R. Response: The purpose of this regulation is to address a number of key Medicaid financing issues and strengthen accountability to ensure compliance with statutory requirements. A State with very few governmentally-operated health care providers that otherwise finances its Medicaid program in a manner consistent with the Federal statute should realize minimal impact from the provisions of this regulation.

236C. Comment: One commenter expressed their extreme dissatisfaction with their perceived disingenuous actions on the part of CMS. The commenter stipulated that they recently worked extensively with CMS to restructure their Medicaid financing and IGTs and were assured by CMS that as restructured they were in compliance with Federal law. However, the commenter pointed out, at the same time that CMS was assuring the commenter that it was in compliance with Federal law, CMS was developing proposed rules that, if applied as written, make CMS' assurance false. The commenter stated that either CMS acted in good faith and it knows that its proposed rules do not accurately reflect Federal law or CMS acted in bad faith because it never intended to fulfill its promises when it restructured the commenters Medicaid financing.

236R. Response: We disagree with this characterization. We have worked extensively with many States in a manner that ensures the financing of their Medicaid programs are consistent with Federal statutory and regulatory requirements. Since August 2003, we have been examining State Medicaid financing through the Medicaid reimbursement SPA review process. During that process, we have worked with several States to identify permissible sources of State Medicaid financing. Over the past few years, many States remained interested in utilizing IGTs (and CPEs) in an effort to help finance their Medicaid programs. During that cooperative review effort, CMS has consistently reminded States the Federal statutory instruction governing IGTs and CPEs. Also during the SPA review process, States informed CMS that they should be allowed to determine eligibility for participation in IGTs (or CPEs) and that, absent clarification in regulation, the States would deem the health care providers they believe to be eligible to IGT or CPE. CMS deferred to that approach and also accommodated States' requests to create greater clarity though regulation to ensure compliance with Federal statute. With the issuance of this regulation, CMS has codified the existing statutory definitions of a unit of government. This codification of existing Federal statute was established in an effort to assist States in identifying the universe of governmentally-operated health care providers that could receive Medicaid revenues up to the full cost of providing services to Medicaid individuals and clarifies which types of health care providers can participate in financing of the non-Federal share of Medicaid payments.

237C. Comment: One commenter took the opportunity to express their strong support for reauthorization of SCHIP and urged CMS to support funding levels that will allow States to maintain coverage for current enrollees, but also expand coverage to children who are eligible, but not yet enrolled.

237R. Response: The reauthorization of SCHIP is outside the scope of this regulation.

238C. Comment: One commenter recommended that CMS immediately consult with States on the proposed rule and modify or withdraw it based on State concerns. The commenter stated that section 5(c) of the Medicaid Voluntary Contribution and Provider-Specific Tax Amendments of 1991 requires the Secretary to ''consult with States before issuing any regulations under this Act.'' The commenter inquired as to whether CMS complied with this statutory mandate since there was no mention of consultation in the preamble to the proposed rule. The commenter was particularly concerned since the National Governors' Association sent a letter to Congress strongly opposing the proposed rule. The commenter also requested information on whether the States' concerns have been taken into consideration at all in the formulation of this proposed rule.

238R. Response: As discussed above, we believe the conditions of section 5(c) of the Medicaid Voluntary Contribution and Provider-Specific Tax Amendments of 1991, Pub. L. 102–234, were fully satisfied by the process the Secretary undertook when the regulations implementing that Act were issued in 1992 and 1993. Even if these conditions were read to extend in perpetuity, however, we believe they have been met with respect to these regulations by the longstanding dialogue with States over these issues, and the employment of notice and comment procedures. The National Governors' Association letter is an example of receipt of State views in this consultation process. Consultation with States does not, however, obligate the federal government to agree with States or cede rulemaking authority to States. This preamble sets forth our consideration of State and other comments.

239C. Comment: One commenter described their current problems involving county government practices related to reimbursement procedures under California Short/Doyle Medi-Cal program. While the issues raised were not directly related to the provisions of the proposed rule, the commenter felt it was important to point out that some counties within the State do not follow the reimbursement requirements within the existing approved Medicaid State plan. The commenter stated that if current practices continue, the proposed rule that providers are reimbursed on the approved Medicaid State plan will continue to be ignored.

239R. Response: It is a State's responsibility to ensure its Medicaid program is implemented in accordance with all Federal Medicaid statutory and regulatory provisions, including compliance with its approved Medicaid State plan. To the extent that any Medicaid payment is not consistent with the methodology in the approved Medicaid State plan, a State is at risk of penalty under the authority of section 1903(a) of the Act and/or section 1904 of the Act and § 430.35.

240C. Comment: Several commenters wrote to express their general concerns about health care in America and the general impact the proposed rule may have on our society. Many of these commenters stated that the financial impact of the proposed rule would cause States, providers, and low-income, elderly, and disabled people throughout the country to suffer, arguing that CMS should not implement any Medicaid rule that involves reductions in Federal Medicaid spending. The general impact of Medicaid cuts on children, in particular, was noted. Some of these commenters suggested that rather than proposing cuts in Medicaid spending, CMS should look for ways to increase Medicaid spending. A number of commenters identified health care for the uninsured, underinsured, and the indigent as a

major issue in the United States today and advocated that everyone should have health coverage. Other commenters suggested that the Federal government should stop wasting taxpayer money in other areas (for example, Federal salaries and benefits, the war in Iraq, other grants to States, etc.) as a means of saving money that could be used to maintain current Medicaid spending.

240R. Response: We agree with the commenters regarding the importance of the Medicaid program to the nation's health care system and the vulnerable individuals that it serves. The provisions of the regulation did not propose the elimination of any funding for health care providers participating in the Medicaid program, or funding for health care services to vulnerable populations including children. We believe that overall this regulation can help strengthen the health care safety net by ensuring proper financing of the Medicaid program.

The purpose of the regulation was to ensure proper State financing of their share of Medicaid program costs in accordance with Federal statutory and regulatory requirements. The regulation was actually designed to protect health care providers, including safety net providers. Under the provisions of the regulation, governmentally-operated health care providers are assured the opportunity to receive full cost reimbursement for serving Medicaid individuals.

Non-governmentally-operated health care providers are not affected by the cost limit provision of the regulation and therefore may continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements. Moreover, one provision of the regulation reaffirmed State Medicaid financing policy requiring that health care providers be allowed to fully retain their Medicaid payments, another provision which clearly demonstrates the Federal government's intent to protect the nation's safety net and its ability to continue delivering critical health care services to Medicaid individuals and the uninsured. In fact, with regard to participation in the State Medicaid financing, non-governmentally-operated health care providers can realize greater net revenues if State or local government funding sources are utilized to fund non-Federal share obligations to Medicaid payments historically financed by non-governmentally operated ''public'' health care providers.

241C. Comment: A number of commenters expressed concern that the proposed rule would have on the continuing viability of the range of services available to adults and children who have serious mental illness. One such commenter opined that individuals who are mentally ill are subjected to low quality health care because States do not pay enough to recruit employees who care about the well being of these individuals.

241R. Response: The provisions of the regulation were not designed to reduce health care services to Medicaid individuals. Instead the Medicaid cost limit permits all governmentally-operated health care providers the opportunity to receive Medicaid revenues up to the full cost of providing services to Medicaid individuals.

Non-governmentally-operated health care providers, including many of the ''public'' safety net health care providers, are not affected by the cost limit provision of the regulation and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements.

Moreover, the regulation reaffirms State Medicaid financing policy requiring that health care providers be allowed to fully retain their Medicaid payments, another provision of which clearly demonstrates the Federal government's intent to protect the nation's public safety net and its ability to continue delivering critical health care services to Medicaid individuals and the uninsured. Any health care providers that become ineligible to participate in the State financing of Medicaid payments following the effective date of the provisions of this regulation can realize greater net revenues if State or local governments choose to utilize their funding sources to fund non-Federal share obligations to Medicaid payments historically financed by non-governmentally-operated ''public'' health care providers.

242C. Comment: A number of commenters wrote in to express displeasure with elected representatives.

242R. Response: This regulation pertains to the financing and fiscal integrity of the Medicaid program. The comments are outside of the scope of the Medicaid program and this regulation.

243C. Comment: A number of commenters expressed concerns about policy issues and other issues that are unrelated to the provisions of this regulation. These issues included immigration policy; inflation; homelessness; veteran's benefits; taxation; personal circumstances; general standards of living; and the war in Iraq.

243R. Response: This regulation pertains to the financing and fiscal integrity of the Medicaid program. The comments are outside of the scope of the Medicaid program and this regulation.

244C. Comment: Some commenters singled out specific providers as being affected by the rule. One commenter opined that the only way that hospitals which treat the uninsured and underinsured can remain in business is from funding received through Disproportionate Share Hospital (DSH) payments and the Upper Payment Limit (UPL). If DSH and UPL programs are eliminated, the commenter asserts, many thousands of people will not receive needed care. Similarly, another commenter stated that many hospitals in a rural State have closed, and more will follow due to inadequate funding. A different commenter worried that nurses would be laid off, resulting in more trips to the emergency room by individuals who would otherwise be treated by nurses at home.

244R. Response: The provisions of the regulation did not propose the elimination of any funding for health care providers participating in the Medicaid program, including DSH funding. Rather the purpose of the regulation is to ensure proper State financing of their share of Medicaid program costs in accordance with Federal statutory and regulatory requirements. The regulation was actually designed to protect health care providers, including safety net providers.

Under the provisions of the regulation, governmentally-operated health care providers are assured the opportunity to receive full cost reimbursement for serving Medicaid individuals. Non-governmentally-operated health care providers are not affected by the cost limit provision of the regulation and therefore may continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements.

Moreover, one provision of the regulation reaffirms State Medicaid financing policy requiring that health care providers be allowed to fully retain their Medicaid payments, another provision which clearly demonstrates the Federal government's intent to protect the nation's safety net and its ability to continue delivering critical health care services to Medicaid individuals and the uninsured. In fact, with regard to participation in the State Medicaid financing, non-

governmentally-operated health care providers can realize greater net revenues if State or local government funding sources are utilized to fund non-Federal share obligations to Medicaid payments historically financed by non-governmentally operated ''public'' health care providers.

245C. Comment: Many commenters strongly urged CMS to withdraw the proposed rule in its entirety. Most of these commenters believe that CMS should meet with impacted stakeholders to develop more meaningful and manageable rules and policy alternatives that would strengthen the nation's health safety net. Other commenters stated that if CMS does not withdraw the proposed rules, States' health care safety nets will unravel and health care services to the nation's most vulnerable individuals will be jeopardized.

245R. Response: The regulation was issued in the **Federal Register** on January 18, 2007 as a notice of proposed rulemaking. A 60-day public comment period was provided and all comments received by CMS have been taken into consideration.

The provisions of the regulation did not propose the elimination of any funding for health care providers participating in the Medicaid program, including DSH funding. Rather the purpose of the regulation is to ensure proper State financing of their share of Medicaid program costs in accordance with Federal statutory and regulatory requirements. The regulation was actually designed to protect health care providers, including safety net providers.

Under the provisions of the regulation, governmentally-operated health care providers are assured the opportunity to receive full cost reimbursement for serving Medicaid individuals. Non-governmentally-operated health care providers are not affected by the cost limit provision of the regulation and therefore may continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements.

Moreover, one provision of the regulation reaffirms State Medicaid financing policy requiring that health care providers be allowed to fully retain their Medicaid payments, another provision which clearly demonstrates the Federal government's intent to protect the nation's safety net and its ability to continue delivering critical health care services to Medicaid individuals and the uninsured. In fact, with regard to participation in the State Medicaid financing, non-governmentally-operated health care providers can realize greater net revenues if State or local government funding sources are utilized to fund non-Federal share obligations to Medicaid payments historically financed by non-governmentally operated ''public'' health care providers.

246C. Comment: Several commenters recommended that CMS meet with various stakeholders to discuss challenges to the proposed rule from both State and Federal funding perspectives, and draft a new regulation that phases in some of the policy proposals.

246R. Response: The regulation was issued in the **Federal Register** on January 18, 2007 as a notice of proposed rulemaking. A 60-day public comment period was provided and all comments received by CMS have been taken into consideration. Further, many provisions of this regulation are mere codifications of Federal Medicaid statutory provisions that CMS has been applying under the examination State Medicaid financing through the Medicaid reimbursement SPA review process. During that process, CMS has worked with several States to identify permissible sources of State Medicaid financing. CMS has consistently reminded States of the Federal statutory instruction governing State financing of the Medicaid program.

247C. Comment: A couple of commenters expressed concern that the proposed rule will have a very serious affect on the ability of rural safety net providers to serve Medicaid individuals and the uninsured while also providing many essential, community-wide services. Another commenter stated that rural counties appear to be disproportionately disadvantaged by the proposed rule, since there are few if any alternative providers not subject to the proposed cost limit which could substitute services previously operated by rural county-operated clinics and the proposed limitations on funding for Medicaid transportation could be disproportionately disadvantageous by isolating seriously mentally disable clients living in rural communities. Another commenter stated that their rural hospital is already reimbursed significantly less than the cost to provide health care services and that any additional cuts will be detrimental to their ability to remain open. One commenter stated that CMS should be able to work with the remaining States to reform their systems without the proposed rule which could have large negative effects on rural government providers. Multiple commenters suggested that the cost limit provision of the proposed rule would disproportionately disadvantage rural providers because many providers in rural communities are governmentally operated, lack medical infrastructure routinely available elsewhere, serve as the only provider in the area, and provide care to a large Medicaid population.

Some commenters expressed concern regarding the impact the substantial cuts the proposed rule will cause on other types of health care providers, including emergency physicians, nurses and physical therapists. With respect to physicians, a commenter stated that as physician practice costs grow, fewer and fewer physicians will be willing to participate in Medicaid, resulting in more and more individuals utilizing emergency room departments and further straining the health care safety net.

Other commenters expressed that the nation's health safety net is fragile and warned against the cuts in Medicaid spending that would occur under the proposed rule, saying that harm to the safety net will ultimately harm the most vulnerable people in our communities.

247R. Response: The provisions of the regulation were not designed to reduce health care services to Medicaid individuals. Instead the Medicaid cost limit permits all governmentally-operated health care providers the opportunity to receive Medicaid revenues up to the full cost of providing services to Medicaid individuals.

Non-governmentally-operated health care providers, including many of the ''public'' safety net health care providers, are not affected by the cost limit provision of the regulation and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements.

Moreover, the regulation reaffirms State Medicaid financing policy requiring that health care providers be allowed to fully retain their Medicaid payments, another provision of which clearly demonstrates the Federal government's intent to protect the nation's public safety net and its ability to continue delivering critical health care services to Medicaid individuals and the uninsured. Any health care providers that become ineligible to participate in the State financing of Medicaid payments following the effective date of the provisions of this regulation can realize greater net revenues if State or local governments choose to utilize their funding sources to fund non-Federal share obligations to Medicaid payments historically

financed by non-governmentally-operated ''public'' health care providers.

248C. Comment: Several commenters urged CMS to reconsider the proposed rules as they will negatively impact delivery of health care services to children and children's hospitals. The commenters stated that because children make up the majority of the Medicaid population, this proposed rule will have a disproportionate impact on them. Some of the commenters also mentioned that on average children's hospitals devote more than 50 percent of their care to children on Medicaid and virtually all care for children with complex health care conditions and therefore they are reliant upon Medicaid (one commenter noted that over 80 percent of their revenues come from Medicaid); such changes to the financing of the program will threaten their financial viability. Another commenter stated that medically disenfranchised children who receive care in community health centers, and at local, regional and State hospitals will face further impediments to access by implementation of this proposed rule.

248R. Response: We do not believe the regulation will compromise the ability of health care providers participating in the Medicaid program from delivering critical health care services to children. Under the provisions of the regulation, governmentally-operated health care providers are assured opportunity to receive full cost reimbursement for serving Medicaid individuals.

Non-governmentally-operated health care providers, including many of the ''public'' safety net hospitals, are not affected by the cost limit provision of the regulation and therefore, may continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements. Moreover, one provision of the regulation reaffirms State Medicaid financing policy requiring that health care providers be allowed to fully retain their Medicaid payments, another provision of which clearly demonstrates the Federal government's intent to protect the nation's public safety net and its ability to continue delivering critical health care services to Medicaid individuals and the uninsured.

249C. Comment: A few commenters stated that overall CMS has usurped Congress' role with respect to Medicaid funding policy. The commenters noted that in the past, when there has been substantial change to Medicaid funding policy (that is, prohibiting provider-related taxes and donations, modifying DSH allotments, or modifying application of UPLs), Congress has made or at least supported the changes. The commenters indicated that if such sweeping changes are to be made to Medicaid, they should be made first through legislation. Another commenter stated that CMS'' response to concerns about lost funding for uninsured health care needs is that it is Congress' job to determine whether such Federal support is needed for Medicaid and uninsured individuals. The commenter pointed out that Congress has expressed no concern with the development of supplemental Medicaid payment systems in which States have used the Medicaid program as the primary source of Federal support for safety net health care. Therefore, if Congress is in fact the only entity, according to CMS, that can authorize replacement funding for the uninsured, then it should also be the entity that considers the types of sweeping payment and financing changes proposed by CMS. In general, many other commenters stated that CMS exceeded its statutory authority with all of the provisions within the proposed rule.

249R. Response: This regulation interprets and implements statutory provisions enacted by Congress. These provisions detail specifically the authority to pay a federal share of the cost of covered services furnished to eligible individuals. Congress has not, to date, provided general authority for Medicaid payment to cover the costs of uncompensated care furnished to the uninsured. Nor has Congress expressly authorized general subsidies for public or safety net providers. Instead, Congress has provided some very specific and limited authority, such as disproportionate share hospital payments, that can be used to cover such costs. The commenters have pointed to no statutory authority to support the general payment of Medicaid funds for non-statutorily authorized purposes. Nor have the commenters explained how it exceeds CMS'' statutory authority to issue a regulation that ensures that Federal Medicaid funding is used for actual costs of covered Medicaid services furnished to eligible individuals.

250C. Comment: Several commenters questioned if according to CMS data there are only three remaining States with questionable Medicaid financing arrangements, why is the proposed rule even necessary. The commenters noted that clearly the steps taken to date by Congress and CMS have addressed the concerns raised by CMS about State Medicaid financing mechanisms. Further the commenters stated that CMS has not explained how the proposed rules will further its stated goals. A few commenters supported CMS'' efforts to address State financing abuses, but believe that this only demonstrates that CMS already has the legal tools and sufficient safeguards under its existing review system and SPA approval process to address these problems and protect the integrity and accountability of the Medicaid program without disturbing the delicate balance between Federal, State, local governments and public health care providers. The commenters urged CMS to continue its work on a State by State basis. Other commenters stated that the proposed rule destroys effective, efficient, and innovative programs previously approved by CMS. Likewise, another commenter stated that the provisions of the proposed rule would diminish long-standing, legitimate State funding mechanisms that CMS has previously approved. A couple of other commenters detailed that CMS and the Office of the Inspector General have aptly demonstrated instances of recycling of Federal funds and of IGTs by entities without public status or funds and the commenters agreed that these abuses should be remedied. However, the commenters do not believe that the proposed rule addresses these abuses and CMS should ensure fair and equitable Medicaid reimbursement to all providers regardless of their operating status.

250R. Response: Although CMS has achieved considerable success in its ongoing compliance monitoring programs on a State-by-State basis, States and providers have repeatedly requested formal clarification of the rules. State-by-State reviews and monitoring are costly and intrusive. This regulation ensures that States will fully understand applicable rules, and will know that the same rules apply nationwide. By setting out clear tests that States can apply and monitor, this regulation will permit States to evaluate potential financing and payment methodologies in advance. Moreover, this regulation will give CMS new enforcement and monitoring tools to ensure compliance.

251C. Comment: A number of commenters were concerned about the workload that will be required to comply with the requirement to update waivers and State plans.

251R. Response: The Medicaid cost limit provision does not require States to necessarily modify existing Medicaid reimbursement systems utilized to make Medicaid payments to governmentally-operated health care providers. Under the Medicaid cost limit States may

continue to use existing Medicaid reimbursement rate methodologies, but will need to compare such rates to the actual cost providing services to Medicaid individuals. Changes to existing Medicaid reimbursement systems deemed necessary by a State are subject to applicable Federal statutory and regulatory requirements.

252C. Comment: A couple of commenters expressed their support for some of the policy objectives associated with this rule. Commenters specifically supported CMS efforts to clarify the regulations governing the financing of the non-Federal share of Medicaid payments; eliminate abusive financing practices involving ''recycling'' of Federal funds; strengthen financial accountability; or limit Federal reimbursement to the reasonable costs of governmental providers for delivering Medicaid services.

252R. Response: We appreciate the support of CMS'' efforts to ensure the fiscal integrity of the Medicaid program.

253C. Comment: Several commenters wrote about the impact the proposed rule could potentially have on teaching hospitals specifically. The commenters noted that teaching hospitals fill unique roles that extend beyond the normative patient care services rendered in other hospitals. For example, teaching hospitals may house level 1 trauma centers, burn centers, cancer centers, and neonatal intensive care units, or they may offer organ transplants, specialized orthopedic services, or high risk obstetrical services. Teaching hospitals are training sites for all types of health professional trainees and have a leading role in medical research, which leads to their care for the nation's sickest and most complex patients.

Teaching hospitals have the newest and most advanced treatments and technologies, and today they are also viewed as front-line responders in the event of a biological, chemical, or nuclear attack or a natural disaster. In many States, teaching hospitals are the only providers of specialized medical services for individuals with serious health conditions. Teaching hospitals also tend to be among the largest Medicaid providers in their States; in fact, one commenter observed that teaching hospitals represent only 6 percent of all hospitals nationally, but about 25 percent of Medicaid discharges are from teaching hospitals. Significant financial investments are necessary for teaching hospitals to continue to fill their critical safety net role in our health care system. The commenters noted that Medicaid is a significant source of revenue for teaching hospitals, commenting that cuts in Medicaid spending and the provisions of the proposed rule could upset the delicate balance of resources that teaching hospitals rely upon to maintain their operations. These commenters suggested that the proposed rule may jeopardize the financial state of teaching hospitals, resulting in potential losses of critical services and reduced access to specialty care.

Another commenter argued that teaching hospitals should not be subject to the proposed cost limit by noting that in prior court filings, CMS has explicitly recognized the value of allowing flexibility for States to direct higher payments to certain hospitals having special needs. The commenter also stated that private hospitals and other hospitals should have the same upper payment limit (UPL) and that a distinct UPL for governmental providers would be unequal and unwarranted.

253R. Response: We agree that teaching hospitals are very important to our nation's ability to deliver health care to all populations, including those with the most critical needs. The regulation reaffirms State Medicaid financing policy requiring that health care providers be allowed to fully retain their Medicaid payments, which clearly demonstrates the Federal government's intent to protect the nation's public safety net and its ability to continue delivering critical health care services to Medicaid individuals and the uninsured. The provisions of the regulation were not designed to reduce health care services to Medicaid individuals. Instead the Medicaid cost limit permits all governmentally-operated health care providers the opportunity to receive Medicaid revenues up to the full cost of providing services to Medicaid individuals. Consistent with the Medicaid cost limit on all governmentally-operated health care providers, the applicable upper payment limit is Medicaid cost. We do not find it appropriate that units of State or local government would ''profit'' from Federal taxpayer dollars that are intended to match a percentage of the cost of providing services to Medicaid individuals.

The DSH program is available to States to provide payments for uncompensated care costs associated with inpatient and outpatient hospital services provided to individuals with no source of third party coverage (that is, uninsured).

254C. Comment: One commenter argued that Section 705(a) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) directed CMS to apply an ''aggregate upper payment limit to payments made to government facilities that are not state-owned or operated facilities.'' The commenter cited this provision in an effort to demonstrate that the proposed cost limit contradicts this mandate from Congress and asked that this provision be rescinded.

254R. Response: Section 705(a) of BIPA set forth conditions for a specific final regulation. Those conditions were met. Section 705(a) did not preclude the Secretary from engaging in further rulemaking on the same subject, or otherwise amend the Social Security Act to require a particular method to implement the requirement at section 1902(a)(30(A) of the Social Security Act to assure payment rates that were consistent with efficiency, economy and quality of care.

255C. Comment: Several commenters were particularly concerned about the impact the proposed cost limit would have on State teaching hospitals. The commenters stated that these facilities typically serve the largest number of Medicaid individuals and provide vital services to the community. Limiting Medicaid payment will eliminate funding for trauma centers and the training of physicians. Another commenter stated the proposed cost limit would foreclose additional opportunities to use UPL supplemental payments to improve reimbursement rates for physicians affiliated with State medical schools.

255R. Response: We agree that teaching hospitals are very important to our nation's ability to deliver health care to all populations, including those with the most critical needs. The regulation reaffirms State Medicaid financing policy requiring that health care providers be allowed to fully retain their Medicaid payments, which clearly demonstrates the Federal government's intent to protect the nation's public safety net and its ability to continue delivering critical health care services to Medicaid individuals and the uninsured. The provisions of the regulation were not designed to reduce health care services to Medicaid individuals. Instead the Medicaid cost limit permits all governmentally-operated health care providers the opportunity to receive Medicaid revenues up to the full cost of providing services to Medicaid individuals. Consistent with the Medicaid cost limit on all governmentally-operated health care providers, the applicable upper payment limit is Medicaid cost. We do not find it appropriate that units of State or local government would ''profit'' from Federal taxpayer dollars that are intended to match a percentage of the

cost of providing services to Medicaid individuals.

The DSH program is available to States to provide payments for uncompensated care costs associated with inpatient and outpatient hospital services provided to individuals with no source of third party coverage (that is, uninsured).

256C. Comment: Many commenters argued that the proposed rule ultimately represents a cost shift from the Federal government to the States. Multiple commenters noted that financing arrangements and reimbursement methodologies which the States have been using for years would now become impermissible under the proposed rule, resulting in a necessary increase of State funds to cover Medicaid program costs. Some commenters opined that States are not equipped to single-handedly shoulder the burden of uncompensated health care costs associated with the rising levels of uninsured in this country. Concern was expressed that States and local governments would be unable to fill the gap created by the loss of Federal funds from this rule, which would stress health care delivery systems across America and result in greater numbers of uninsured and reduced access to care. Therefore, these commenters urged CMS to withdraw the proposed rule.

Many other commenters expressed a belief that despite assertions by CMS, the proposed regulation is actually nothing more than an effort to cut Federal Medicaid spending.

256R. Response: The Federal government remains committed to funding its share of the cost of providing Medicaid services to eligible individuals. Further, we understand that governmentally-operated health care providers have numerous goals and objectives that extend beyond the Medicaid program. Under the Medicaid cost limit of the regulation, Medicaid will continue to be permitted to pay for its share of costs associated with a provider's services that benefit Medicaid individuals in accordance with applicable statutory and regulatory requirements. However, when Medicaid is viewed as a primary source of revenue for a government's non-Medicaid activities, no matter how noble such activities may be, the statutory purpose of the Medicaid program has been undermined. Medicaid is a shared responsibility between Federal and State government. State governments may share their fiscal obligation to the Medicaid program with local governments according to the instruction of Congress. However, States are responsible for ensuring that their administration of their Medicaid program is in compliance with all Federal statutory and regulatory requirements. We do not find it appropriate that units of State or local government would ''profit'' from Federal taxpayer dollars that are intended to match a percentage of the cost of providing services to Medicaid individuals.

The provisions of the regulation were not designed to reduce health care services to Medicaid individuals. Instead the Medicaid cost limit permits all governmentally-operated health care providers the opportunity to receive Medicaid revenues up to the full cost of providing services to Medicaid individuals. Non-governmentally-operated health care providers, including many of the ''public'' health care providers, are not affected by the Medicaid cost limit provision and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements.

Moreover, the regulation reaffirms State Medicaid financing policy requiring that health care providers be allowed to fully retain their Medicaid payments, another provision of which clearly demonstrates the Federal government's intent to protect the nation's public safety net and its ability to continue delivering critical health care services to Medicaid individuals and the uninsured. Any health care providers that become ineligible to participate in the State financing of Medicaid payments following the effective date of this regulation can realize greater net revenues if State or local government funding sources are utilized to fund non-Federal share obligations to Medicaid payments historically financed by non-governmentally-operated ''public'' health care providers.

257C. Comment: Many commenters wrote about the impact that the proposed rule would have on specific States, communities, or providers throughout the country. Although it is not possible to cite every specific situation that was cited, a few examples are provided here. One commenter, a large city government, noted the high levels of Medicaid individuals within its jurisdiction but the disproportionately low level of dollars received for Medicaid services, arguing that the proposed rule will severely restrict the level and quality of care provided to city residents. A commenter estimated that within its State, 80 DSH hospitals, 65 UPL hospitals, 78 nursing homes, 12 ICF/MR facilities, 159 public health departments, and 27 community mental health centers would be impacted by the rule, concluding that the statewide health care safety net ''is anticipated to collapse'' due to the rule. A State medical association asserted that public hospitals in the State's largest communities would lose $338 million in Federal Medicaid funds as a result of this rule. Another commenter stated that the proposed rule would cut off existing Federal funding streams to its State, forcing hospitals to either raise their charges to insured individuals or reduce costs by eliminating costly but under-reimbursed services, neither of which was desirable. The commenter went on to say that the ultimate economic impact of the rule on the State, including the loss of Federal Medicaid funding and the associated loss of jobs and other economic impacts, has been estimated at over $600 million statewide. An additional commenter conveyed statistics about the services safety net providers offer and the populations they serve within the State, urging CMS to do nothing that could lower reimbursements to such providers. The comments cited are representative generally of the opinions expressed about the impact the proposed rule would have on specific States, localities, and providers. For the most part, commenters who wrote about such specific impacts opposed the rule and asked CMS to withdraw it.

257R. Response: The Federal government remains committed to funding its share of the cost of providing Medicaid services to eligible individuals. Further, we understand that governmentally-operated health care providers have numerous goals and objectives that extend beyond the Medicaid program. Under the Medicaid cost limit of the regulation, Medicaid will continue to be permitted to pay for its share of costs associated with a provider's services that benefit Medicaid individuals in accordance with applicable statutory and regulatory requirements. However, when Medicaid is viewed as a primary source of revenue for a government's non-Medicaid activities, no matter how noble such activities may be, the statutory purpose of the Medicaid program has been undermined. Medicaid is a shared responsibility between Federal and State government. State governments may share their fiscal obligation to the Medicaid program with local governments according to the instruction of Congress. However, States are responsible for ensuring that their administration of their Medicaid program is in compliance with all

Federal statutory and regulatory requirements. We do not find it appropriate that units of State or local government would ''profit'' from Federal taxpayer dollars that are intended to match a percentage of the cost of providing services to Medicaid individuals.

The provisions of the regulation were not designed to reduce health care services to Medicaid individuals. Instead the Medicaid cost limit permits all governmentally-operated health care providers the opportunity to receive Medicaid revenues up to the full cost of providing services to Medicaid individuals. Non-governmentally-operated health care providers, including many of the ''public'' health care providers, are not affected by the Medicaid cost limit provision and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements.

Moreover, the regulation reaffirms State Medicaid financing policy requiring that health care providers be allowed to fully retain their Medicaid payments, another provision of which clearly demonstrates the Federal government's intent to protect the nation's public safety net and its ability to continue delivering critical health care services to Medicaid individuals and the uninsured. Any health care providers that become ineligible to participate in the State financing of Medicaid payments following the effective date of this regulation can realize greater net revenues if State or local government funding sources are utilized to fund non-Federal share obligations to Medicaid payments historically financed by non-governmentally-operated ''public'' health care providers.

258C. Comment: A number of commenters recognized that some States, local governments, or providers have been involved in abusive Medicaid financing practices but asserted that the proposed rule, in its effort to address such abuses, actually penalizes those who did not engage in inappropriate financing practices. These commenters argued that it is unfair that States, local governments, or providers who have done nothing wrong are now paying for the misdeeds of others. Numerous other commenters argued that the proposed cost limit is overreaching and CMS is improperly imposing this restrictive limit in States that either removed or never relied on inappropriate financing arrangements. They believe the new cost limit would impose a deep cut to rectify a non-existent problem in most instances.

258R. Response: The Federal government remains committed to funding its share of the cost of providing Medicaid services to eligible individuals. Further, we understand that governmentally-operated health care providers have numerous goals and objectives that extend beyond the Medicaid program. Under the Medicaid cost limit of the regulation, Medicaid will continue to be permitted to pay for its share of costs associated with a provider's services that benefit Medicaid individuals in accordance with applicable statutory and regulatory requirements. However, when Medicaid is viewed as a primary source of revenue for a government's non-Medicaid activities, no matter how noble such activities may be, the statutory purpose of the Medicaid program has been undermined. Medicaid is a shared responsibility between Federal and State government. State governments may share their fiscal obligation to the Medicaid program with local governments according to the instruction of Congress. However, States are responsible for ensuring that their administration of their Medicaid program is in compliance with all Federal statutory and regulatory requirements. We do not find it appropriate that units of State or local government would ''profit'' from Federal taxpayer dollars that are intended to match a percentage of the cost of providing services to Medicaid individuals.

The provisions of the regulation were not designed to reduce health care services to Medicaid individuals. Instead the Medicaid cost limit permits all governmentally-operated health care providers the opportunity to receive Medicaid revenues up to the full cost of providing services to Medicaid individuals. Non-governmentally-operated health care providers, including many of the ''public'' health care providers, are not affected by the Medicaid cost limit provision and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements.

Moreover, the regulation reaffirms State Medicaid financing policy requiring that health care providers be allowed to fully retain their Medicaid payments, another provision of which clearly demonstrates the Federal government's intent to protect the nation's public safety net and its ability to continue delivering critical health care services to Medicaid individuals and the uninsured. Any health care providers that become ineligible to participate in the State financing of Medicaid payments following the effective date of this regulation can realize greater net revenues if State or local government funding sources are utilized to fund non-Federal share obligations to Medicaid payments historically financed by non-governmentally-operated ''public'' health care providers.

259C. Comment: One commenter questioned why cost reporting is necessary for publicly-operated health care providers who do not participate in the non-federal share of Medicaid payments and who retain all of their Medicaid payments.

259R. Response: The Federal Medicaid statute does not include a term nor discussion that references a ''public'' health care provider for purposes of State Medicaid financing. We do not believe the cost limit will impose significant administrative burden on States particularly since such limit applies only to governmentally-operated health care providers.

For purposes of institutional governmentally-operated health care providers, the Medicaid cost limit determination will rely on existing reporting tools used by institutional health care providers. States will not be required to audit financial and cost information provided by individual institutional governmentally-operated health care providers as part of the Medicaid cost limit review. Each of the source documents is subject to reporting and auditing rules specific to the original purpose of that document and independent of the Medicaid cost limit and State review process. The State must render an determination on the cost limit methodology applied to the source documents but will not be required to validate the accuracy of the information and data within the source documents.

For non-institutional services provided to Medicaid eligible individuals, a nationally recognized, standard cost report currently does not exist. Because of this, we will be publishing a standardized cost reporting form that should be used to document such services. The purpose of this standardized form is to document in a uniform manner the cost of providing non-institutional services to Medicaid individuals. The period of time to which this cost report applies will be the Medicaid State plan rate year.

CMS has modified the regulation to include a transition period to allow States and governmentally operated non-institutional health care providers

sufficient time to develop and implement Medicaid cost documentation and reporting processes consistent with the cost report template issued by CMS (including but not limited to changes in State/provider reporting systems, changes to the Medicaid State plan, changes to time studies, establish periodic review and audit processes, etc.), States will not be required to document and report cost information associated with non-institutional Medicaid services until the State's Medicaid State plan rate year 2009. Actual submission of the State's summary report on the Medicaid cost limit for non-institutional services will not be due to CMS until December 31, 2011, which allows States an opportunity to implement periodic review and audit processes for Medicaid non-institutional costs starting in Medicaid State plan rate year 2009.

CMS has developed a general Medicaid Cost Reporting Protocol available on the CMS website that specifically addresses the methods under which institutional and non-institutional Medicaid costs will be determined. The protocol was designed to provide States with detailed instructions to determine compliance with Federal requirements.

IV. Provisions of the Final Regulations

[If you choose to comment only on issues related to Unit of Government Definition (§ 433.50) in this section, please include the caption ''Provisions of the Final Regulations'' at the beginning of your comments.]

As a result of our review of the comments we received during the public comment period, as discussed in section III of this preamble, we are making the following revisions to the regulation published on January 18, 2007.

Section 433.50—Definition of Unit of Government

We have modified the regulation at § 433.50 to address concerns regarding taxing authority as a requirement for an entity to be considered a unit of government. The regulation has been revised to indicate that a unit of government is a State, a city, a county, a special purpose district, or other governmental unit in the State that has taxing authority or direct access to tax revenues. We have added the phrase ''has direct access to tax revenues'' to recognize as governmental those entities that do not have taxing authority, but do have direct access to tax revenues that are imposed by a parent or related unit of government. For example, when a tax is imposed and collected by a State but is dedicated for use by a municipality or other entity, that entity would satisfy the criteria of direct access to tax revenues. Similarly, a county-operated hospital that is recognized in the county's budget to receive local tax subsidies via the county appropriation process, and without the need to contract for such tax revenues, would satisfy the criteria of direct access to tax revenues. We have deleted the phrase ''generally applicable'' because we do not believe it is necessary since the provider tax rules already require that permissible taxes be broad based and uniform. But we interpret the term ''taxing authority'' in this context to exclude authority to levy user fees in exchange for benefits specific to the payer, even though those fees would be considered a tax for other purposes.

We have also modified the regulation to recognize the explicit reference to State university teaching hospitals in section 1903(w)(6)(A) of the Act. We have added § 433.50(a)(1)(ii)(C) to recognize State university teaching hospitals as a unit of government eligible to participate in the financing of the non-Federals hare of Medicaid payments.

We have also modified the regulation at § 433.50 to address concerns raised about the unique governance arrangements of Indian tribes and tribal organizations. Specifically, paragraph § 433.50(a)(1)(i) has been modified to consider as a unit of government ''an Indian tribe as defined in section 4 of the Indian Self-Determination and Education Assistance Act, as amended.'' Additionally, we have amended proposed language at § 433.50(a)(1)(ii) by adding a new section (D) to define the criteria under which a health care provider operated by a tribe or tribal organization may also be considered a unit of government under this section. This criteria is consistent with policy articulated in State Medicaid Director (SMD) letters previously issued on October 18, 2005 and June 9, 2006.

Section 447.206—Cost Limit for Providers Operated by Units of Government

In the summary section of the proposed regulation, we indicated that Medicaid managed care organizations (MCOs) are not subject to the Medicaid cost limit provision of this regulation, but this was not expressly identified in § 447.206. In recognition of existing statutory and regulatory instruction applicable to Medicaid reimbursement to Medicaid MCOs, Prepaid Inpatient Health Plans (PIHPs) and Prepaid Ambulatory Health Plans (PAHPs) we have modified the regulation at § 447.206(b) to specifically exempt MCOs, PIHPs and PAHPs from the Medicaid cost limit.

In addition, in recognition of existing statutory instruction applicable to Medicaid reimbursement to Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs), we have modified the regulation at § 447.206(b) to also specifically exempt FQHCs and RHCs from the Medicaid cost limit.

In addition to the exceptions listed above, § 447.206(b) has also been modified to exclude disproportionate share hospital (DSH) payments from the Medicaid cost limit provision at § 447.206. DSH payment adjustments are instead subject to limitations and requirements under section 1923 of the Act.

A primary purpose of the regulation was to limit Medicaid payments to governmentally operated health care providers to the cost of providing services to Medicaid individuals. States will have an obligation to ensure that Medicaid reimbursements to governmentally operated health care providers do not exceed the individual governmentally operated health care provider's costs of serving Medicaid individuals (the newly established a ''cost limit''). CMS has modified the regulation and developed protocols in an effort to address concerns regarding requirements to properly document, audit, and review the costs associated with the provision of Medicaid services in both institutional and non-institutional environments.

1. Institutional Providers

The Medicare cost allocation process utilized for institutional health care providers is considered a key component in determining Medicaid cost under the rule. Institutional governmentally-operated health care providers (i.e. hospitals, nursing facilities, and intermediate care facilities for the mentally retarded (ICFs/MR)) will be required to provide the State with data extracted from primary source documents as well as copies of the source documents. These documents would include the provider's Medicare cost report (or Medicaid cost report for intermediate nursing facility care and ICFs/MR consistent with Medicare cost reporting principles), and audited financial statements that will be used in conjunction with information provided by the States' Medicaid Management Information Systems (MMIS).

CMS has modified the regulation to provide that the State's review of Medicaid payments to institutional governmentally operated providers to

ensure compliance with the cost limit during Medicaid State Plan rate year 2008 must be completed no later than the last day of federal fiscal year 2010. The State must submit a summary report of the findings of this review by the last day of calendar year of 2010. The basis for these deadlines is the recognition that hospitals, nursing homes and ICFs/MR may have a cost reporting period that remains open after the Medicaid State Plan rate year under review has ended. The State review and reporting deadlines allow sufficient time for the cost report period that remains open at the end of a Medicaid State Plan rate year to close and for the cost report to be submitted to the fiscal intermediary. For any cost reports that are not finalized by the fiscal intermediary, the State should use the ''as filed'' report and indicate such in the summary report to CMS. The State should then submit a corrected summary report to CMS within 30 days of the finalization of the cost report.

2. Non-Institutional Providers

For all non-institutional services provided to Medicaid eligible individuals, we note that a nationally recognized, standard cost report does not exist. Because of this, we are publishing a standardized cost reporting form that should be used to document such services. The purpose of this standardized form is to document in a uniform manner the cost of providing non-institutional services to Medicaid individuals.

CMS has modified the regulation to include a transition period to allow States and governmentally operated non-institutional providers sufficient time to develop and implement Medicaid cost documentation and reporting processes consistent with the cost report template issued by CMS (including but not limited to changes in State/provider reporting systems, changes to the Medicaid State plan, changes to time studies, etc.), States will not be required to document and report cost information associated with non-institutional Medicaid services until the State's Medicaid State plan rate year 2009. Actual submission of the State's summary report on the Medicaid cost limit for non-institutional services will not be due to CMS until December 31, 2011, which allows States an opportunity to establish periodic review and audit processes for Medicaid non-institutional costs starting in Medicaid State plan rate year 2009.

CMS has developed a general Medicaid Cost Reporting Protocol available on the CMS website that specifically addresses the information utilized from each source document and the methods under which institutional and non-institutional Medicaid costs will be determined. The protocol was designed to provide States with detailed instructions to determine compliance with the Federal requirements.

Each subsequent State review of Medicaid payments to governmentally operated health care providers, after the Medicaid State plan rate years identified above, must be performed annually and completed by the last day of the federal fiscal year ending two years from the Medicaid State plan rate year under review. Each State must submit a summary report to CMS showing the results of the State's review of payments to ensure compliance with the Medicaid cost limit for governmentally-operated health care providers by the last day of the calendar year ending two years from the Medicaid State plan rate year under review.

Section 447.207—Retention of Payments

We have revised some of the introductory wording of this provision to make clear that the requirements of this section are applicable to State Medicaid payment methodologies and do not impose a specific mandate on providers. We have also added a paragraph (b) to § 447.207 to note that payments authorized by Sections 701(d) and 705 of the Benefits Improvement Act of 2000 (BIPA), taxes that are permissible under Section 1903(w) of the Act, and normal operating expenses of conducting business shall not be questioned for purposes of compliance with the provision.

Section 447.321—Outpatient Hospital and Clinic Services: Application of Upper Payment Limits

To address concerns that § 447.321 does not identify disproportionate share hospital payments (DSH) as an exception to the Medicaid cost limit and to maintain consistency with the purpose of the Medicaid cost limit and with the statutory provision governing DSH at section 1923 of the Act, § 447.321(c) has been modified to include an exemption for DSH payment adjustments from the application of outpatient hospital upper payment limit.

1. Payments authorized by the Benefits Improvement Act of 2000 (BIPA)

To address concerns about the impact the proposed regulation might have on payments authorized by Sections 701(d) and 705 of the Benefits Improvement Act of 2000 (BIPA), we have modified the regulation at § 447.207, § 447.272, and § 447.321 to clarify that these unique and statutorily authorized payments are not subject to the upper payment limits or retention provisions of this regulation.

2. ''Tool to Evaluate the Governmental Status of Health Care Provider'

States will be required to apply the statutory and regulatory criteria to each individual health care provider to make initial determinations of governmental status. In connection with the proposed regulation, CMS published an instrument to collect information about the governmental nature of health care providers, referenced herein as the ''Tool to Evaluate the Governmental Status of Health Care Provider.'' Based on comments received, this tool has been modified to guide States in applying the statutory and regulatory criteria to make the initial determination of a health care provider's governmental status and to create a record supporting this determination relative to each governmentally operated health care provider in the State.

States will be required to keep copies of each completed ''Tool to Evaluate the Governmental Status of Health Care Provider'' form on file in order to maintain a record of the official State determination regarding the governmentally operated status of individual health care providers. States must report the universe of governmental health care providers in each State by submitting a complete list of such providers to the Associate Regional Administrator for Medicaid of each State's respective CMS Regional Office within 90 days of the effective date of the regulation. CMS reserves the right to disagree with a State's initial determination of governmental status if we believe the State has not consistently applied the statutory and regulatory criteria. In addition, States will be required to submit these forms to CMS for any Medicaid institutional and non-institutional reimbursement State plan amendments and as requested under Medicaid financial management reviews performed by CMS.

V. Collection of Information Requirements

[If you choose to comment only on issues related to Unit of Government Definition (§ 433.50) in this section, please include the caption ''Collection of Information Requirements'' at the beginning of your comments.]

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is

submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

Section 433.51 Public Funds as the State Share of Financial Participation

Section 433.51 requires that a certified public expenditure (CPE) be supported by auditable documentation in a form(s) approved by the Secretary that, at a minimum, identifies the relevant category of expenditures under the Medicaid State Plan, demonstrates the cost of providing services to Medicaid recipients, and is subject to periodic State audit and review.

The burden associated with this requirement is the time and effort put forth by a provider to complete the approved form(s) to be submitted with a CPE. Depending upon provider size, we believe that it could take approximately 10–80 hours to fill out the form(s) that would be required for an annual certified public expenditure. We estimate that governmentally-operated health care providers in 50 States will be affected by this requirement. The total number of health care providers affected and the estimated total aggregate hours of paperwork burden for all health care providers (that is, both institutional and non-institutional government health care providers) will be a direct result of the number of health care providers that are determined to be governmentally-operated.

Section 447.206 Cost Limit for Providers Operated by Units of Government

Section 447.206(e) states that each governmentally-operated health care provider must submit annually a cost report to the Medicaid agency which reflects the individual governmentally-operated health care provider's cost of serving Medicaid recipients during the year. The Medicaid Agency must review the cost report to determine that costs on the report were properly allocated to Medicaid and verify that Medicaid payments to the governmentally-operated health care provider during the year did not exceed the governmentally-operated health care provider's cost.

States will have an obligation to ensure that Medicaid reimbursements to governmentally operated health care providers do not exceed the individual governmentally operated health care provider's costs of serving Medicaid individuals (the newly established ''cost limit''). CMS has modified the regulation and developed protocols in an effort to address concerns regarding requirements to properly document, audit, and review the costs associated with the provision of Medicaid services in both institutional and non-institutional environments.

The Medicare cost allocation process utilized for institutional health care providers is considered a key component in determining Medicaid cost under the rule. Institutional governmentally-operated health care providers (i.e. hospitals, nursing facilities, and intermediate care facilities for the mentally retarded (ICFs/MR)) will be required to provide the State with data extracted from primary source documents as well as copies of the source documents. These documents would include the provider's Medicare cost report (or CMS-approved cost report for intermediate nursing facility care and ICFs/MR consistent with Medicare cost reporting principles), and audited financial statements that will be used in conjunction with information provided by the States' Medicaid Management Information Systems (MMIS). The protocols provide guidance regarding the methodology States must utilize for determining Medicaid costs associated with these existing cost reporting documents.

For all non-institutional services provided to Medicaid eligible individuals, we note that a nationally recognized, standard cost report does not exist. Because of this, we are establishing a standardized cost reporting form that should be used to document such services. The purpose of this standardized form is to document in a uniform manner the cost of providing non-institutional services to Medicaid individuals. We will submit this information collection for the non-institutional cost documentation to OMB for its review and approval. This information collection is not effective until OMB approves it.

The burden associated with this requirement is the time and effort for the institutional governmentally-operated health care provider to report the cost information annually to the Medicaid Agency and the time and effort involved in the review and verification of the report by the Medicaid Agency. We estimate that it will take a governmentally-operated health care provider 1 hour to prepare and submit the report annually to the Medicaid Agency. We estimate it will take the Medicaid Agency 1 to 10 hours to review and verify the information provided. We are unable to identify the total number of governmentally-operated health care providers affected or the estimated total aggregate hours of paperwork burden for all governmentally-operated health care providers, as such this information will be a direct result of the number of health care providers that are determined to be governmentally operated.

The burden associated with this requirement is the time and effort for the governmentally-operated health care provider to report the cost information annually to the Medicaid Agency and the time and effort involved in the review and verification of the report by the Medicaid Agency. We estimate that it will take a governmentally-operated health care provider 2 to 90 hours to prepare and submit the report annually to the Medicaid Agency. We estimate it will take the Medicaid Agency 1 to 10 hours to review and verify the information provided. We are unable to identify the total number of governmentally-operated health care providers affected or the estimated total aggregate hours of paperwork burden for all governmentally-operated health care providers, as such this information will be a direct result of the number of health care providers that are determined to be governmentally operated.

In the preamble of this final regulation, under the section titled ''*Tool to Evaluate Governmental Status of Providers*'', we discuss a form questionnaire that we have developed to assist us in making a determination as to whether or not the health care provider is a unit of government. We will submit this information collection to OMB for its review and approval. This information collection is not effective until OMB approves it.

As required by section 3504(h) of the Paperwork Reduction Act of 1995, we have submitted a copy of this final regulation to OMB for its review of these information collection requirements described above.

If you comment on these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attn.: Melissa Musotto, CMS–2258–FC, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Katherine T. Astrich, CMS Desk Officer, CMS–2258–FC, *Katherine_T._Astrich@omb.eop.gov*. Fax (202) 395–6974.

VI. Regulatory Impact Analysis

[If you choose to comment only on issues related to Unit of Government Definition (§ 433.50) in this section, please include the caption ''Regulatory Impact Analysis'' at the beginning of your comments.]

A. Introduction

We have examined the impacts of this regulation as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6.5 million to $31.5 million in any 1 year. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. For the reasons cited below, we have determined that this regulation may have a significant impact on small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $120 million. We are not imposing any unfunded mandates on States that would rise to the $120 million threshold level established by Section 202 of the Unfunded Mandates Reform Act of 1995.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. The provisions of this regulation were designed to ensure consistent application of the Federal statutory instructions regarding the definition of a unit of government for purposes of Medicaid reimbursement and State financing. States continue to maintain flexibility, within Federal statute and regulation, to decide on medically necessary services that will be covered, populations that will be covered and rates that will be paid to health care providers. This regulation merely ensures the fiscal integrity of the Medicaid program. Consistent with this analysis, for purposes of Executive Order 13132, we do not find that this regulation will have a substantial effect on State or local governments.

B. Costs and Benefits

This rule is a major rule because it is estimated to result in $120 million in savings during the first year and $3.87 billion in savings over five years.

As CMS has examined Medicaid State financing arrangements across the country, we have identified numerous instances in which State financing practices do not comport with the Medicaid statute. Since the summer of 2003, we have reviewed and processed over 1,400 State plan amendments related to State payments to health care providers. Through this examination we have developed a greater understanding of how to ensure that payment and financing arrangements comply with statutory intent. We found that many States make supplemental payments to governmentally-operated health care providers that are in excess of cost. These health care providers, in turn, use that excess of Medicaid revenue over cost to subsidize health care (or other) operations that are unrelated to Medicaid, or they may return a portion of the supplemental payments in excess of cost to the States and/or local government. This regulation strengthens accountability to ensure that statutory requirements within the Medicaid program are met in accordance with sections 1902, 1903, and 1905 of the Act.

As explained in the background section of the preamble, section 1903(w) of the Act permits units of government to participate in the financing of the non-Federal share; however, in some instances States rely on funding from non-governmental entities for the non-Federal share. Because such practices are expressly prohibited by the donations and taxes amendments at section 1903(w) of the Act, we are issuing this regulation to clarify the requirements of entities and health care providers that are able to finance the non-Federal share.

Arrangements in which health care providers did not retain the full amount of their Medicaid payments is inappropriate and inconsistent with statutory construction that the Federal government pays only its proportional cost for the delivery of Medicaid services. When a State claims Federal reimbursement in excess of net payments to health care providers, the FMAP rate has effectively been increased, and federal Medicaid funds are redirected toward non-Medicaid services. When a State chooses to recycle FFP in this manner, the Federal taxpayers in other States disproportionately finance the Medicaid program in the State that is recycling FFP. This regulation is designed to eliminate such practices.

The regulation should also have a beneficial distributive impact on governmentally-operated health care providers because in many States there are a few selected governmentally-operated health care providers receiving payments in excess of cost, while other governmentally-operated health care providers receive a lower rate of reimbursement. This regulation will reduce inflated payments to those few

governmentally-operated health care providers and promote a more even distribution of funds among all governmentally-operated health care providers. This is because all governmentally-operated health providers will be limited to a level of reimbursement that does not exceed the individual governmentally-operated health care provider's cost of providing services to Medicaid individuals.

We have observed that there are a variety of practices used by State and local governments in identifying costs and submitting a CPE as the basis of matching FFP for the provision of Medicaid services. These different cost methods and CPE practices make it difficult to (1) align claimed expenditures with specific services covered under the State plan or identifiable administrative activities; (2) properly identify the actual cost to the governmental entity of providing services to Medicaid recipients or performing administrative activities; and (3) audit and review Medicaid claims to ensure that Medicaid payments are appropriately made. Such circumstances present risks of inflationary costs being certified and excessive claims of FFP. This regulation will facilitate a more consistent methodology in Medicaid cost identification and allocation across the country, thereby improving the fiscal integrity of the program.

Because the RFA includes small governmental jurisdictions in its definition of small entities, we expect this regulation to have a significant economic impact on a substantial number of small entities, specifically health care providers that are operated by units of government, including governmentally-operated small rural hospitals, as they will be subject to the new Medicaid cost limit imposed by this regulation. We have previously reviewed CMS'' Online Survey and Certification and Reporting System (OSCAR) data for information about select provider types that may be impacted by this rule. According to the OSCAR data, there are:

- 1,153 hospitals that have identified themselves as operated by local governments or hospital districts/authorities;
- 822 nursing facilities that have identified themselves as operated by counties, cities, or governmental hospital districts;
- 113 intermediate care facilities for the mentally retarded (ICF/MR) that have identified themselves as operated by cities, towns, or counties.

We have not counted State operated facilities in the above numbers because for purposes of the RFA, States are not included in the definition of a small entity. Note further that OSCAR data is self-reported, so the figures provided above do not necessarily reflect the number of governmentally-operated health care providers according to the provisions of this regulation.

Small governmental jurisdictions (population under 50,000) may be impacted by this regulation depending upon their responsibilities for participating in financing of the non-Federal share of Medicaid payments and other governmental obligations to uninsured individuals. If a governmentally-operated health care provider within the small governmental jurisdiction was receiving Medicaid payments in excess of its Medicaid costs of providing health care services to Medicaid individuals, the governmentally-operated health care provider will experience a reduction in Medicaid revenues. While this itself would not result in a direct impact on the small governmental jurisdiction there could be an indirect impact. If the small governmental jurisdiction was not responsible for financing the non-Federal share of such payments and those Medicaid payments above cost were being used to subsidize uninsured health care costs, the small governmental jurisdiction may now have to subsidize the uninsured health care costs out of its own revenues.

On the other hand, if the small governmental jurisdiction was responsible for financing the non-Federal share of Medicaid payments above the individual governmentally-operated health care provider's Medicaid costs, it will no longer have to finance Medicaid payments above costs. The small governmental jurisdiction could then use these previously obligated revenues to satisfy other costs or obligations within its jurisdiction.

This analysis is not unique to small governmental jurisdictions and would hold true for both States and larger local governmental jurisdictions.

Under the provisions of the regulation, all governmentally-operated health care providers will be permitted to receive no more than 100 percent of the cost of serving Medicaid individuals. Some of the governmentally-operated health care providers identified as small entities for RFA purposes may have been receiving Medicaid payments in excess of cost. If a health care provider operated by a small unit of government has been historically receiving Medicaid payments above cost and using excess Medicaid revenues to subsidize other costs outside of the Medicaid program, this regulation would cause a net reduction in revenue to the health care provider.

Governmentally-operated health care providers, including those operated by small units of local government, that are not receiving Medicaid payments in excess of costs would not be adversely impacted by the Medicaid cost limit and would be eligible to receive greater Medicaid revenues, up to the cost limit.

There are health care providers that are considered under the RFA as small entities (including small rural hospitals) but are not governmentally operated; to the extent these providers have been involved in financing the non-Federal share of Medicaid payments, this regulation will clarify whether or not such practices may continue. Non-governmentally-operated health care providers are not affected by the cost limit provision of the regulation and may therefore continue to receive Medicaid payments in excess of the cost of providing services to Medicaid individuals within existing Federal requirements.

Moreover, the provisions of the regulation reaffirm State Medicaid financing policy requiring that health care providers be allowed to fully retain their Medicaid payments. Any health care providers that become ineligible to participate in the State financing of Medicaid payments following the effective date of the provisions of this regulation can realize greater net revenues if State or local government funding sources are utilized to fund non-Federal share obligations to Medicaid payments historically financed by non-governmentally-operated ''public'' health care providers. On the other hand, if States reduce payment rates to such governmentally operated health care providers after this regulation is effective, such governmentally-operated health care providers may experience a decrease in net revenue.

As stated earlier, for purposes of the RFA, the small entities principally affected by this regulation are governmentally-operated health care providers. In light of the specific universe of small entities impacted by the regulation, the fact that this regulation requires States to allow governmentally-operated health care providers to receive and retain their Medicaid payments, and the allowance for governmentally operated health care providers to receive a Medicaid rate up to cost, we have not identified a need for regulatory relief under the RFA.

Ultimately, this regulation is designed to ensure that Medicaid payments to governmentally-operated health care

providers are based on actual costs of providing services to Medicaid individuals and that the financing arrangements supporting those payments are consistent with the statute. While some health care providers may lose revenues in light of this rule, those revenues were likely in excess of Medicaid cost or may have been financed using methods that did not permit the health care provider to retain Medicaid payments received. Other health care providers that were adversely affected by questionable reimbursement and financing arrangements may now, under this regulation, benefit from a more equitable distribution of funds. Private health care providers are generally unaffected by this rule, except for limited situations where the clarification provided by the regulation may require a change to current financing arrangements.

With respect to clinical care, we anticipate that this regulation's effect on actual patient services to be minimal. The regulation presents no changes to coverage or eligibility requirements under Medicaid. The rule clarifies statutory financing requirements and allows governmentally-operated health care providers to be reimbursed at levels up to the full cost of providing services to Medicaid individuals. Federal matching funds will continue to be made available based on expenditures for appropriately covered and financed services. While States may need to change reimbursement or financing methods, we do not anticipate that services delivered by governmentally-operated health care providers or private health care providers will change.

C. Anticipated Effects

The following chart summarizes our estimate of the anticipated effects of this regulation.

ESTIMATED REDUCTION IN FEDERAL MEDICAID OUTLAYS RESULTING FROM THE PROVIDER PAYMENT REFORM PROPOSAL BEING IMPLEMENTED BY CMS–2258–P

[Amounts in millions]

	Fiscal year				
	2007	2008	2009	2010	2011
Payment Reform	−120	−530	−840	−1,170	−1,210

These estimates are based on recent reviews of state Medicaid spending. Payment reform addresses both spending through intergovernmental transfers (IGT) and limiting payments to governmentally-operated health care providers to the cost or providing services to Medicaid individuals. For IGT spending, recent reports on spending on Disproportionate Share Hospitals (DSH) and Upper Payment Limit (UPL) spending were reviewed. From these reports, an estimate of the total spending that would be subject to the net expenditure policy was developed and then projected forward using assumptions consistent with the most recent President's Budget projections. The estimate of the savings in federal Medicaid spending as a result of this policy factors in the current authority and efforts of CMS and the impact of recent waivers; the estimate also accounts for the potential effectiveness of future efforts. There is uncertainty in this estimate to the extent that the projections of IGT spending may not match actual future spending and to the extent that the effectiveness of this policy is greater than or less than assumed.

Reports on UPL spending following the most recent legislation concerning UPL were reviewed to develop a projection for total enhanced payments in Medicaid spending. The estimate of savings from this policy reflects both estimates of the amount of UPL spending that exceeds cost and the effectiveness of this policy in limiting payments to cost. The estimate also accounts for transitional UPL payments, which are unchanged under this policy, and for the impact of recent waivers. There is uncertainty in this estimate to the extent that the projections of UPL spending may not match actual future spending, to the extent that the amount of UPL spending above cost differs from the estimated amount, and to the extent that the effectiveness of this policy is greater than or less than assumed.

D. Alternatives Considered

In developing this regulation various options were considered. We considered seeking to implement policies requiring provider retention of payments, greater accountability for certified public expenditures, and clarification of the definition of a unit of government without any new regulation (using existing statutory and regulatory authority). We determined that the rulemaking process would be a more effective method of implementing these policies because the rulemaking process would better inform affected parties, allow for public input, and make clear that the standards set forth are uniform, fair and consistent with the underlying statutory intent.

We considered deferring to States and local governments to define which entities are units of government for purposes of Medicaid financing. We considered this possibility of deferring to State determinations, but we concluded that it was important for effective oversight review to receive standardized information under a clear, uniform and enforceable standard.

Similarly, we considered allowing governmentally-operated health care providers to be reimbursed at current rates and not be limited to the cost of serving Medicaid individuals. Given the information CMS has gathered regarding the use of Medicaid payments to governmentally-operated health care providers, we find that the provision to limit governmentally-operated health care providers to Medicaid cost offers a way to reasonably reimburse governmentally-operated health care providers while ensuring that Federal matching funds are used for their intended purpose, which is to pay for a covered Medicaid service to a Medicaid beneficiary and not non-Medicaid activities.

Likewise, we considered the option of limitomg only those governmentally-operated health care providers that participate in IGTs and CPEs to the cost of providing Medicaid services to Medicaid individuals. However, we believe it is not appropriate that units of State or local government would ''profit'' from Federal taxpayer dollars that are intended to match a percentage of the cost of providing services to Medicaid individuals. We do not find that Medicaid payments in excess of cost to governmentally-operated health care providers are consistent with the statutory principles of economy and efficiency.

With respect to the timeframe for implementation of the Medicaid cost

limit to governmentally-operated health care providers of non-institutional services, we considered requiring compliance with the effective date of the regulation. However, a nationally recognized, standard cost report does not exist for non-institutional services, we allow States and governmentally-operated health care providers sufficient time to develop and implement Medicaid cost documentation and reporting processes. Likewise, we considered providing a similar delay in implementation for governmentally-operated institutional health care providers, but since there are existing standardized, nationally recognized cost reporting mechanisms we did not believe a delay was appropriate.

E. Accounting Statement

As required by OMB Circular A–4 (available at MACROBUTTON HtmlResAnchor *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in the table below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this regulation. This table provides our best estimate of the decrease in Federal Medicaid outlays resulting from the provider payment reform requirements being implemented by CMS–2258–P (Cost Limit for Providers Operated by Units of Government and Provisions to Ensure the Integrity of Federal-State Financial Partnerships). The sum total of these expenditures is classified as savings in Federal Medicaid spending.

ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FISCAL YEAR 2007 TO FISCAL YEAR 2011

[In millions]

Category	Transfers
Annualized Monetized Transfers	Negative Transfer-Estimated decrease in expenditures: $774.
From Whom To Whom?	Federal Government to States.

F. Conclusion

We expect that this regulation will promote the fiscal integrity of the Medicaid program. The regulation will enhance accountability for States to properly finance the non-Federal share of Medicaid expenditures and allow them to pay reasonable rates to governmentally-operated health care providers. To the extent prior Medicaid payments to governmentally-operated health care providers were inflated, the regulation will reduce such payments to levels that more accurately reflect the actual cost of Medicaid services and ensure that the non-Federal share of Medicaid payments has been satisfied in a manner consistent with the statute. Private health care providers are predominately unaffected by the regulation, and the effect on actual patient services should be minimal.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 433

Administrative practice and procedure, Child support, Claims, Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 447

Accounting, Administrative practice and procedure Drugs, Grant programs-health, Health facilities, Health professions, Medicaid Reporting and recordkeeping requirements, Rural areas.

42 CFR Part 457

Administrative practice and procedure, Grant programs-health, Health insurance, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 433—STATE FISCAL ADMINISTRATION

■ 1. The authority citation for part 433 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

■ 2. Amend § 433.50 by revising paragraph (a)(1) to read as follows:

§ 433.50 Basis, scope, and applicability.

(a) * * *

(1) Section 1902(a)(2) and section 1903(w)(7)(G) of the Act, which require States to share in the cost of medical assistance expenditures and permit State and local units of government to participate in the financing of the non-Federal portion of medical assistance expenditures.

(i) A unit of government is a State, a city, a county, a special purpose district, or other governmental unit in the State that: has taxing authority, has direct access to tax revenues, is a State university teaching hospital with direct appropriations from the State treasury, or is an Indian tribe as defined in Section 4 of the Indian Self-Determination and Education Assistance Act, as amended [25 U.S.C. 450b].

(ii) A health care provider may be considered a unit of government only when it is operated by a unit of government as demonstrated by a showing of the following:

(A) The health care provider has generally applicable taxing authority; or

(B) The health care provider has direct access to generally applicable tax revenues. This means the health care provider is able to directly access funding as an integral part of a unit of government with taxing authority which is legally obligated to fund the health care provider's expenses, liabilities, and deficits, so that a contractual arrangement with the State or local government is not the primary or sole basis for the health care provider to receive tax revenues;

(C) The health care provider receives appropriated funding as a State university teaching hospital providing supervised teaching experiences to graduate medical school interns and residents enrolled in a State university in the State; or

(D) The health care provider is an Indian Tribe or Tribal organization (as those terms are defined in Section 4 of the Indian Self-Determination and Education Assistance Act (ISDEAA); 25 U.S.C. 450b) and meets the following criteria:

(*1*) If the entity is a Tribal organization, it is—

(*a*) Carrying out health programs of the IHS, including health services which are eligible for reimbursement by Medicaid, under a contract or compact entered into between the Tribal organization and the Indian Health Service pursuant to the Indian Self-Determination and Education

Assistance Act, Public Law 93–638, as amended, and

(*b*) Either the recognized governing body of an Indian tribe, or an entity which is formed solely by, wholly owned or comprised of, and exclusively controlled by Indian tribes.

* * * * *

■ 3. Section 433.51 is revised to read as follows:

§ 433.51 Funds from units of government as the State share of financial participation.

(a) Funds from units of government may be considered as the State's share in claiming FFP if they meet the conditions specified in paragraphs (b) and (c) of this section.

(b) The funds from units of government are appropriated directly to the State or local Medicaid agency, or are transferred from other units of government (including Indian tribes) to the State or local agency and are under its administrative control, or are certified by the contributing unit of government as representing expenditures eligible for FFP under this section. Certified public expenditures must be expenditures within the meaning of 45 CFR 95.13 that are supported by auditable documentation in a form approved by the Secretary that, at a minimum—

(1) Identifies the relevant category of expenditures under the State plan;

(2) Explains whether the contributing unit of government is within the scope of the exception to limitations on provider-related taxes and donations;

(3) Demonstrates the actual expenditures incurred by the contributing unit of government in providing services to eligible individuals receiving medical assistance or in administration of the State plan; and

(4) Is subject to periodic State audit and review.

(c) The funds from units of government are not Federal funds, or are Federal funds authorized by Federal law to be used to match other Federal funds.

PART 447—PAYMENTS FOR SERVICES

■ 1. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

■ 2. Section 447.206 is added to read as follows:

§ 447.206 Cost limit for providers operated by units of government.

(a) *Scope.* This section applies to payments made to health care providers that are operated by units of government as defined in § 433.50(a)(1) of this chapter.

(b) *Exceptions.* The limitation in paragraph (c) of this section does not apply to:

(1) Indian Health Services facilities and tribal facilities that are funded through the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638);

(2) Managed Care Organizations (MCOs), Prepaid Inpatient

Health Plans (PIHPs), and Prepaid Ambulatory Health Plans (PAHPs) which are organized and operating in accordance with the provisions of 42 CFR 438;

(3) Federally Qualified Health Centers (FQHCs) and Rural

Health Clinics (RHCs) reimbursed in accordance with Section 1902(bb) of the Act; and

(4) *Disproportionate share hospital payments.* The limitation in paragraph (c) of this section does not apply to payment adjustments made under section 1923 of the Act that are made under a State plan to hospitals found to serve a disproportionate number of low-income patients with special needs as provided in section 1902(a)(13)(A)(iv) of the Act. Disproportionate share hospital (DSH) payments are subject to the following limits:

(i) The aggregate DSH limit using the Federal share of the DSH limit under section 1923(f) of the Act.

(ii) The hospital-specific DSH limit in section 1923(g) of the Act.

(iii) The aggregate DSH limit for institutions for mental disease (IMDs) under section 1923(h) of the Act.

(a) *General rules.* (1) All health care providers that are operated by units of government are limited to reimbursement not in excess of the individual health care provider's cost of providing covered Medicaid services to eligible Medicaid recipients.

(2) Reasonable methods of identifying and allocating costs to Medicaid will be determined by the Secretary in accordance with sections 1902, 1903, and 1905 of the Act, as well as 45 CFR 92.22 and Medicare cost principles when applicable.

(3) Institutional governmentally-operated health care providers (i.e., hospitals, nursing facilities, and ICFs/MR) are required to provide the State with data extracted from primary source documents as well as copies of the source documents. These source documents would include the health care provider's Medicare cost report (or Medicaid cost report for intermediate nursing facility care and ICFs/MR consistent with Medicare cost reporting principles, and audited financial statements that will be used in conjunction with information provided by the States' Medicaid Management Information System (MMIS).

(4) Medicaid costs for non-institutional governmentally-operated health care providers must be supported by auditable documentation in a form approved by the Secretary that is consistent with § 433.51(b)(1) through (b)(4) of this chapter.

(d) *Use of certified public expenditures.* This paragraph applies when States use a cost reimbursement methodology funded by certified public expenditures.

(1) In accordance with paragraph (c) of this section, each provider must submit annually a cost report to the Medicaid agency that reflects the individual provider's cost of serving Medicaid recipients during the year.

(2) States may utilize most recently filed cost reports to develop interim rates and may trend those interim rates by an applicable health care-related index. Interim reconciliations must be performed by reconciling the interim Medicaid payment rates to the filed cost report for the spending year in which interim payment rates were made.

(3) Final reconciliation must be performed annually by reconciling any interim payments to the finalized cost report for the spending year in which any interim payment rates were made.

(4) Non-institutional governmentally-operated health care providers must utilize a cost report, approved by the Secretary, beginning in their Medicaid State plan rate year 2009. Interim rates set by States for purposes of Medicaid payments funded by certified public expenditures in Medicaid State plan rate year 2009 must be calculated based on cost data from at least one quarter of their Medicaid State plan rate year 2008 documented in accordance with the cost report approved by the Secretary. Existing certified public expenditure methodologies can be used to make Medicaid payments during Medicaid State plan rate year 2008.

(e) *Payments not funded by certified public expenditures.* This paragraph applies to payments made to providers operated by units of government that are not funded by certified public expenditures. In accordance with paragraph (c) of this section, each provider must submit annually a cost report to the Medicaid agency that reflects the individual provider's cost of serving Medicaid recipients during the year. The Medicaid agency must review the cost report to determine that costs on the report were properly allocated to Medicaid and verify that Medicaid

payments to the provider during the year did not exceed the provider's cost.

(f) *Overpayments.* If, under paragraph (d) or (e) of this section, it is determined that a governmentally-operated health care provider received an overpayment, amounts related to the overpayment will be properly credited to the Federal government, in accordance with part 433, subpart F of this chapter.

(g) *Compliance dates.* Initial compliance dates have been separately established for institutional and non-institutional Medicaid providers operated by units of government. Following initial compliance dates, ongoing compliance will be consistent for all providers operated by units of government. A State must comply with the Medicaid cost limit described in paragraph (c) of this section in accordance with the timeframes and requirements in paragraphs (g)(1) through (g)(3) of this section.

(1) *Initial Compliance for Institutional Govermentally-Operated Health Care Providers.* For each State, compliance with the Medicaid cost limit described in paragraph (c) of this section applicable to institutional governmentally-operated health care providers begins with the Medicaid State plan rate year 2008. A State's review of Medicaid payments made to institutional governmentally-operated health care providers to ensure compliance with the Medicaid cost limit during Medicaid State plan rate year 2008 must be completed no later than the last day of federal fiscal year 2010 (September 30, 2010). The State must submit to CMS a summary report of the findings of this review by the last day of calendar year of 2010 (December 31, 2010). For any cost reports that are not finalized, the State should use the ''as filed'' cost report and indicate such in the summary report to CMS. The State should then submit a corrected summary report to CMS within 30 days of the finalization of the cost report.

(2) *Initial Compliance for Non-Institutional Governmentally-Operated Health Care Providers.* For each State, compliance with the cost limit described in paragraph (c) of this section applicable to non-institutional governmentally-operated health care providers begins with the Medicaid State plan rate year 2009. A State's review of Medicaid payments made to non-institutional governmentally-operated health care providers to ensure compliance with the Medicaid cost limit during Medicaid State plan rate year 2009 must be completed no later than the last day of federal fiscal year 2011 (September 30, 2011). The State must submit to CMS a summary report of the findings of this review by the last day of calendar year of 2011 (December 31, 2011).

(3) *Ongoing Compliance for Institutional and Non-Institutional Governmentally-Operated Health Care Providers.* Each subsequent State review of Medicaid payments made to governmentally-operated health care providers, after the Medicaid State plan rate years identified in paragraphs (g)(1) and (g)(2) of this section, must be performed annually and completed by the last day of the federal fiscal year ending two years from the Medicaid State plan rate year under review. Each State must submit a summary report to CMS demonstrating the results of the State's review of Medicaid payments to ensure compliance with the Medicaid cost limit applicable to governmentally-operated health care providers by the last day of the calendar year ending two years from the Medicaid State Plan rate year under review.

(i) For any cost reports that are not finalized at the time the State performs the review of Medicaid payments to institutional governmentally-operated health care providers, the State should use the ''as filed'' cost report and indicate such in the summary report to CMS. The State should then submit a corrected summary report to CMS within 30 days of the finalization of the cost report.

■ 3. Section 447.207 is added to read as follows:

§ 447.207 Retention of payments.

(a) Payment methodologies must permit the provider to receive and retain the full amount of the total computable payment for services furnished under the approved State plan (or the approved provisions of a waiver or demonstration if applicable). The Secretary will determine compliance with this provision by examining any associated transactions that are related to the provider's total computable payment to ensure that the State's claimed expenditure, which serves as the basis for Federal Financial Participation, is equal to the State's net expenditure, and that the full amount of the non-Federal share of the payment has been satisfied.

(b) *Exceptions.* Provisions of paragraph (a) of this section specifically do not pertain to:

(1) Use of Medicaid revenues to fund payments that are normal operating expenses of conducting business, such as payments related to taxes (including permissible health-care related taxes), fees, or business relationships with governments unrelated to Medicaid in which there is no connection to Medicaid payment.

(2) Payments authorized by Sections 701(d) and 705 of the Benefits Improvement Act of 2000 (BIPA).

■ 4. Section § 447.271 is revised to read as follows:

§ 447.271 Upper limits based on customary charges.

(a) The agency may not pay a provider more for inpatient hospital services under Medicaid than the provider's customary charges to the general public for the services.

(b) [Reserved]

■ 5. Section 447.272 is amended by revising paragraphs (a) through (d) to read as follows:

§ 447.272 Inpatient services: Application of upper payment limits.

(a) *Scope.* This section applies to rates set by the agency to pay for inpatient services furnished by hospitals, nursing facilities, and ICFs/MR within one of the following categories:

(1) State government operated facilities (that is, all facilities that are operated by the State) as defined at § 433.50(a) of this chapter.

(2) Non-State government operated facilities (that is, all governmentally operated facilities that are not operated by the State) as defined at § 433.50(a) of this chapter.

(3) Privately operated facilities, that is, all facilities that are not operated by a unit of government as defined at § 433.50(a) of this chapter.

(b) *General rules.* (1) For privately operated facilities, upper payment limit refers to a reasonable estimate of the amount that would be paid for the services furnished by the group of facilities under Medicare payment principles in subchapter B of this chapter.

(2) For State government operated facilities and for non-State government operated facilities, upper payment limit refers to the individual health care provider's Medicaid cost as defined at § 447.206.

(3) Except as provided in paragraph (c) of this section, aggregate Medicaid payments to the group of privately operated facilities described in paragraph (a) of this section may not exceed the upper payment limit described in paragraph (b)(1) of this section.

(4) Except as provided in paragraph (c) of this section, Medicaid payments to State government operated facilities and non-State government operated facilities must not exceed the individual health care provider's Medicaid cost as documented in accordance with § 447.206.

(c) *Exceptions—(1) Indian Health Services and tribal facilities.* The limitation in paragraph (b) of this section does not apply to Indian Health Services facilities and tribal facilities that are funded through the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638).

(2) *Disproportionate share hospitals.* The limitation in paragraph (b) of this section does not apply to payment adjustments made under section 1923 of the Act that are made under a State plan to hospitals found to serve a disproportionate number of low-income patients with special needs as provided in section 1902(a)(13)(A)(iv) of the Act. Disproportionate share hospital (DSH) payments are subject to the following limits:

(i) The aggregate DSH limit using the Federal share of the DSH limit under section 1923(f) of the Act.

(ii) The hospital-specific DSH limit in section 1923(g) of the Act.

(iii) The aggregate DSH limit for institutions for mental disease (IMDs) under section 1923(h) of the Act.

(3) The limitation in paragraph (b) of this section does not apply to payments authorized by Sections 701(d) and 705 of the Benefits Improvement Protection Act of 2000 (BIPA).

(d) *Compliance dates.* Except as permitted under paragraph (e) of this section, a State must comply with the upper payment limit described in paragraph (b) of this section by one of the following dates:

(1) For State government operated and non-State government operated hospitals, nursing facilities and ICFs/MR '' Medicaid State plan rate year 2008.

(2) For all other facilities—March 13, 2001.

* * * * *

■ 6. Section 447.321 is amended by revising paragraphs (a) through (d) to read as follows:

§ 447.321 Outpatient hospital and clinic services: Application of upper payment limits.

(a) *Scope.* This section applies to rates set by the agency to pay for outpatient services furnished by hospitals and clinics within one of the following categories:

(1) State government operated facilities (that is, all facilities that are operated by the State) as defined at § 433.50(a) of this chapter.

(2) Non-State government operated facilities (that is, all governmentally operated facilities that are not operated by the State) as defined at § 433.50(a) of this chapter.

(3) Privately operated facilities that is, all facilities that are not operated by a unit of government as defined at § 433.50(a) of this chapter.

(b) *General rules.* (1) For privately operated facilities, upper payment limit refers to a reasonable estimate of the amount that would be paid for the services furnished by the group of facilities under Medicare payment principles in subchapter B of this chapter.

(2) For State government operated facilities and for non-State government operated facilities, upper payment limit refers to the individual health care provider's Medicaid cost as defined at § 447.206.

(3) Except as provided in paragraph (c) of this section, aggregate Medicaid payments to the group of privately operated facilities within one of the categories described in paragraph (a) of this section may not exceed the upper payment limit described in paragraph (b)(1) of this section.

(4) Except as provided in paragraph (c) of this section, Medicaid payments to State government operated facilities and non-State government operated facilities must not exceed the individual health care provider's Medicaid cost as documented in accordance with § 447.206.

(c) *Exceptions—(1) Indian Health Services and tribal facilities.* The limitation in paragraph (b) of this section does not apply to Indian Health Services facilities and tribal facilities that are funded through the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638).

(2) *Disproportionate share hospitals.* The limitation in paragraph (b) of this section does not apply to payment adjustments made under section 1923 of the Act that are made under a State plan to hospitals found to serve a disproportionate number of low-income patients with special needs as provided in section 1902(a)(13)(A)(iv) of the Act. Disproportionate share hospital (DSH) payments are subject to the following limits:

(i) The aggregate DSH limit using the Federal share of the DSH limit under section 1923(f) of the Act.

(ii) The hospital-specific DSH limit in section 1923(g) of the Act.

(iii) The aggregate DSH limit for institutions for mental disease (IMDs) under section 1923(h) of the Act.

(3) The limitation in paragraph (b) of this section does not apply to payments authorized by Sections 701(d) and 705 of the Benefits Improvement Protection Act of 2000 (BIPA).

(d) *Compliance dates.* Except as permitted under paragraph (e) of this section, a State must comply with the upper payment limit described in paragraph (b) of this section by one of the following dates:

(1) For State government operated and non-State government operated hospitals—Medicaid State plan rate year 2008.

(2) For State government operated and non-State government operated clinics—Medicaid State plan rate year 2009.

(3) For all other facilities—March 13, 2001.

* * * * *

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 1. The authority for part 457 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

■ 2. Section 457.220 is revised to read as follows:

§ 457.220 Funds from units of government as the State share of financial participation.

(a) Funds from units of government may be considered as the State's share in claiming FFP if they meet the conditions specified in paragraphs (b) and (c) of this section.

(b) The funds from units of government are appropriated directly to the State or local Medicaid agency, or are transferred from other units of government (including Indian tribes) to the State or local agency and are under its administrative control, or are certified by the contributing unit of government as representing expenditures eligible for FFP under this section. Certified public expenditures must be expenditures within the meaning of 45 CFR 95.13 that are supported by auditable documentation in a form approved by the Secretary that, at a minimum—

(1) Identifies the relevant category of expenditures under the State plan;

(2) Explains whether the contributing unit of government is within the scope of the exception to limitations on provider-related taxes and donations;

(3) Demonstrates the actual expenditures incurred by the contributing unit of government in providing services to eligible individuals receiving medical assistance or in administration of the State plan; and

(4) Is subject to periodic State audit and review.

(c) The funds from units of government are not Federal funds, or are Federal funds authorized by Federal law to be used to match other Federal funds.

■ 3. Amend § 457.628 by—
■ A. Republishing the introductory text to the section.
■ B. Revising paragraph (a).

The republication and revision read as follows:

§ 457.628 Other applicable Federal regulations.

Other regulations applicable to SCHIP programs include the following:

(a) HHS regulations in § 433.50 through § 433.74 of this chapter (sources of non-Federal share and Health Care-Related Taxes and Provider-Related Donations) and § 447.207 of this chapter (Retention of payments) apply to States' SCHIP programs in the same manner as they apply to States' Medicaid programs.

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(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: May 23, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: May 23, 2007.

Michael O. Leavitt,

Secretary.

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