DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 482 and 485

[CMS–3244–F]

RIN 0938–AQ89

Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: This final rule revises the requirements that hospitals and critical access hospitals (CAHs) must meet to participate in the Medicare and Medicaid programs. These changes are an integral part of our efforts to reduce procedural burdens on providers. This rule reflects the Centers for Medicare and Medicaid Services' (CMS) commitment to the general principles of the President's Executive Order 13563, released January 18, 2011, entitled ''Improving Regulation and Regulatory Review.''

DATES: These regulations are effective on July 16, 2012.

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SUPPLEMENTARY INFORMATION:

Executive Summary for This Final Rule

A. Purpose

In Executive Order 13563, ''Improving Regulations and Regulatory Review'', the President recognized the importance of a streamlined, effective, and efficient regulatory framework designed to promote economic growth, innovation, job-creation, and competitiveness. To achieve a more robust and effective regulatory framework, the President has directed each executive agency to establish a plan for ongoing retrospective review of existing significant regulations to identify those rules that can be eliminated as obsolete, unnecessary, burdensome, or counterproductive or that can be modified to be more effective, efficient, flexible, and streamlined. This final rule responds directly to the President's instructions in Executive Order 13563 by reducing outmoded or unnecessarily burdensome rules, and thereby increasing the ability of hospitals and CAHs to devote resources to providing high quality patient care.

B. Summary of the Major Provisions

Revisions To Allow Flexibility and Eliminate Burdensome Conditions of Participation (CoPs): We have reduced burden to providers and suppliers by modifying, removing, or streamlining current regulations that we have identified as excessively burdensome.

- *Single governing body for multiple hospitals:* We will allow one governing body to oversee multiple hospitals in a multi-hospital system and have added a requirement for a member, or members, of the hospital's medical staff to be included on the governing body as a means of ensuring communication and coordination between a single governing body and the medical staffs of individual hospitals in the system.
- *Reporting of Restraint-Related Deaths:* We have replaced the requirement that hospitals must report deaths that occur while a patient is only in soft, 2-point wrist restraints with a requirement that hospitals must maintain a log (or other system) of all such deaths. This log must be made available to CMS immediately upon request. We have indicated that the log is internal to the hospital and that the name of the practitioner responsible for the care of the patient may be used in the log in lieu of the name of the attending physician if the patient was under the care of a non-physician practitioner and not a physician.
- *Role of other practitioners on the Medical Staff:* We have broadened the concept of ''medical staff'' and have allowed hospitals the flexibility to include other practitioners as eligible candidates for the medical staff with hospital privileges to practice in the hospital in accordance with State law. All practitioners will function under the rules of the medical staff. This change will clearly permit hospitals to allow other practitioners (e.g., APRNs, PAs, pharmacists) to perform all functions within their scope of practice. We have required that the medical staff must examine the credentials of all eligible candidates (as defined by the governing body) and then make recommendations for privileges and medical staff membership to the governing body.
- *Medical staff leadership:* We have allowed podiatrists to be responsible for the organization and conduct of the medical staff. This change will allow podiatrists to assume a new leadership role within hospitals, if hospitals so choose.
- *Nursing care plan:* We have allowed hospitals the options of having a stand-alone nursing care plan or a single interdisciplinary care plan that addresses nursing and other disciplines.
- *Administration of medications:* We have allowed hospitals to have an optional program for patient(s)/support person(s) on self-administration of appropriate medications. The program must address the safe and accurate administration of specified medications; ensure a process for medication security; address self-administration training and supervision; and document medication self-administration.
- *Administration of blood transfusions and intravenous medications:* We have eliminated the requirement for non-physician personnel to have special training in administering blood transfusions and intravenous medications and have revised the requirement to clarify that those who administer blood transfusions and intravenous medications do so in accordance with State law and approved medical staff policies and procedures. We believe that this clarification will make the requirement consistent with current standards of practice.
- *Orders by other practitioners:* We have allowed for drugs and biologicals to be prepared and administered on the orders of practitioners (other than a doctor), in accordance with hospital policy and State law, and have also allowed orders for drugs and biologicals to be documented and signed by practitioners (other than a doctor), in accordance with hospital policy and State law.
- *Standing Orders:* We have allowed hospitals the flexibility to use standing orders and have added a requirement for medical staff, nursing, and pharmacy to approve written and electronic standing orders, order sets, and protocols. We have required that orders and protocols must be based on nationally recognized and evidence-based guidelines and recommendations.
- *Verbal Orders:* We have eliminated the requirement for authentication of verbal orders within 48-hours and have deferred to applicable State law to establish authentication timeframes.
- *Authentication of Orders:* We have made permanent the previous temporary requirement that all orders, including verbal orders, must be dated, timed, and authenticated by either the ordering practitioner or another practitioner who is responsible for the care of the patient and who is authorized to write orders by hospital policy in accordance with State law.

• *Infection Control Log:* We have eliminated the obsolete requirement for a hospital to maintain an infection control log. Hospitals are already required to monitor infections and do so through various surveillance methods including electronic systems.

• *Outpatient services director:* We have removed the burdensome and outdated requirement for a single Director of Outpatient Services position that oversees all outpatient departments in a hospital. Hospitals already have separate directors for individual outpatient departments, so having a single overall Director position is duplicative and unnecessary.

• *Transplant Center Process Requirements:* We have eliminated a duplicative requirement for an organ recovery team that is working for the transplant center to conduct a ''blood type and other vital data verification'' before organ recovery when the recipient is known. The verification will continue to be completed at two other times in the transplant process.

• *CAH Provision of Services:* We have eliminated the burdensome requirement that CAHs must furnish diagnostic and therapeutic services, laboratory services, radiology services, and emergency procedures directly by CAH staff. This will allow CAHs to provide such services under arrangement.

Clarifying Changes: We have clarified several requirements in the hospital and CAH CoPs to ensure that they are consistent with the statute as well as with other, more current CoP requirements.

• *Pharmaceutical Services:* We have made a technical change to replace the term ''quality assurance program'' with the more current term ''quality assessment and performance improvement program.''

• *Infection Control:* We have made a technical change to replace the term ''quality assurance program'' with the more current term ''quality assessment and performance improvement program.''

• *CAH Personnel Qualifications:* We have aligned the definition of ''clinical nurse specialist'' that is in the rule with the definition that is in the statute.

• *CAH Surgical Services:* We have clarified that ''surgical services'' are an optional service for CAHs.

Other Options Considered: We discussed alternative options for revisions that we considered, but did not propose. In the proposed rule, we also solicited comments and suggestions from both stakeholders and the general public on additional reforms that would reduce burden on hospitals and CAHs. In this rule, we have included our responses to the comments received on those alternatives, as well as a summary of additional recommendations submitted by commenters.

C. Summary of Costs and Benefits

1. Overall Impact

The rule will reduce the total regulatory burden for hospitals and CAHs by nearly $940 million initially and by almost $5 billion over the next five years. Changes to the following CoPs accounted for the greatest potential savings in the final rule: § 482.22, Medical staff ($330 million); § 482.23, Nursing services ($110 million); § 482.24, Medical record services ($170 million); and § 482.54, Outpatient services ($300 million). Our estimates were based on input from stakeholders as well as on our own experience with hospitals.

The potential savings will be achieved through a number of significant regulatory changes. For example, changes to the Medical staff CoP will allow hospitals to broaden the concept of ''medical staff'' through the appointment of non-physician practitioners to the medical staff so that they may perform the duties for which they are qualified through training and education and as allowed within their State scope-of-practice laws. For hospitals that choose this option, significant savings might be achieved as non-physician practitioners will enable physicians to more effectively manage their time so that they may focus on the more medically complex patients. Changes to the Nursing services CoP will allow hospitals to have a stand-alone nursing care plan or a single interdisciplinary care plan that addresses nursing and other disciplines. Providing hospitals with the option for a single, interdisciplinary care plan for each patient that addresses nursing and other disciplines, will not only support and improve the coordination of patient care, it will also result in significant cost reductions and efficiencies.

The revisions will also allow hospitals much greater flexibility and freedom to determine the best ways to oversee and manage outpatients by removing the outdated requirement for a single Director of Outpatient Services. This simple, but necessary change to the Outpatient services CoP will bring hospitals both cost savings and more efficient ways to manage hospital resources. Finally, we will now allow CAHs to provide diagnostic and therapeutic services, laboratory services, radiology services, and emergency procedures under arrangement. For these small hospitals, this change will not only allow them to solve some of their pressing staffing problems in these service areas, it will allow them to increase access to these critical services for their patient populations.

While we feel confident that our estimates reflect a reasonable approach to hospital and CAH cost savings, much will depend on the future staffing and management decisions that individual hospitals and CAHs choose to make.

2. Section-by-Section Economic Impact Estimates for 2012

	Section	Annual savings ($M)	Five year savings ($M)
Patient's Rights—Eliminate and replace burdensome reporting process for deaths involving only soft wrist restraints	482.13	$5.1	$25.5
Medical Staff—Flexibility to consider other practitioners as eligible candidates for the medical staff	482.22	330.0	1,650.0
Nursing Services—Eliminate requirement for nursing care plan when an interdisciplinary plan is already in place	482.23	110.0	550.0
Medical Record Services—Less burdensome process to authenticate verbal orders	482.24	80.0	400.0
Medical Record Services—Allow the use of pre-printed and electronic standing orders for patient orders	482.24	90.0	450.0
Infection Control—Eliminate log of incidents related to infections and communicable diseases	482.42	6.6	33.0
Outpatient Services—Allow one or more individuals to be responsible for the supervision of outpatient services	482.54	300.0	1,500.0
Transplant Organ recovery—Remove duplicative blood typing requirement	482.92	0.2	1.0

	Section	Annual savings ($M)	Five year savings ($M)
CAH Provision of Services—Eliminate the requirement that certain services be provided only by employees and not through contractual arrangements with entities such as community physicians, laboratories, or radiology services	485.635	15.8	79.0
Total		937.7	4,688.5

Acronyms

AHA American Hospital Association
AOA American Osteopathic Association
APRN Advanced Practice Registered Nurse
BBA Balanced Budget Act
CAH Critical Access Hospital
CCN CMS Certification Number
CDC Centers for Disease Control and Prevention
CfC Condition for Coverage
CoP Condition of Participation
CMS Centers for Medicare & Medicaid Services
CNS Certified Nurse Specialist
DNV Det Norske Veritas
EACH Essential Access Community Hospital
H&P History and Physical Examination
HAI Healthcare-Associated Infection
HFAP Healthcare Facilities Accreditation Program
HHS U.S. Department of Health and Human Services
IG Interpretive Guidelines
IOM Institute of Medicine
MRHFP Medicare Rural Hospital Flexibility Program
OBRA Omnibus Budget Reconciliation Act
OPO Organ Procurement Organization
PA Physician Assistant
RIA Regulatory Impact Analysis
RFA Regulatory Flexibility Act
RPCH Rural Primary Care Hospital
SBA Small Business Administration
SBREFA Small Business Regulatory Enforcement Fairness Act
SOM State Operations Manual
TJC The Joint Commission
UMRA Unfunded Mandates Reform Act

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I. Background

A. Introduction

This final rule reflects the Centers for Medicare and Medicaid Services' (CMS) commitment to the general principles of the President's Executive Order 13563, released January 18, 2011, entitled ''Improving Regulation and Regulatory Review.'' In this final rule we seek to reduce the regulatory burden placed on hospitals. We have identified a number of existing hospital Conditions of Participations (CoPs) that we believe could be reformed, simplified, or eliminated in order to reduce unnecessary burden and costs placed on hospitals and critical access hospitals (CAHs) under existing regulations. The January 2011 Executive Order directs agencies to select the least burdensome approaches, to minimize cumulative costs, to simplify and harmonize overlapping regulations, and to identify and consider flexible approaches that maintain freedom of choice for the American public. Executive Order 13563 also requires agencies to engage in a process of reviewing existing regulations to see if those rules make sense and continue to be justified. The provisions of this final rule are intended to meet the letter and spirit of Executive Order 13563, for reviewing existing regulations to see if those rules make sense and continue to be justified. They also meet the objectives of section 610 of the Regulatory Flexibility Act (RFA), which also requires agencies to review the impact of existing rules on small businesses or other small entities for possible reforms to reduce burden and costs.

B. Statutory and Regulatory Authority for Hospital CoPs

Sections 1861(e)(1) through (8) of the Social Security Act (the Act) provide that a hospital participating in the Medicare program must meet certain specified requirements. Section 1861(e)(9) of the Act specifies that a hospital also must meet such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals furnished services in the institution. Under this authority, the Secretary has established regulatory requirements that a hospital must meet to participate in Medicare at 42 CFR Part 482, CoPs for Hospitals. Section 1905(a) of the Act provides that Medicaid payments from States may be applied to hospital services. Under regulations at 42 CFR 440.10(a)(3)(iii), 42 CFR 440.20(a)(3)(ii), and 42 CFR 440.140, hospitals are required to meet the Medicare CoPs in order to participate in Medicaid.

On May 26, 1993, CMS published a final rule in the **Federal Register** entitled ''Medicare Program; Essential Access Community Hospitals (EACHs) and Rural Primary Care Hospitals (RPCHs)'' (58 FR 30630) that implemented sections 6003(g) and 6116 of the Omnibus Budget Reconciliation Act (OBRA) of 1989 and section 4008(d) of OBRA 1990. That rule established requirements for the EACH and RPCH providers that participated in the seven-State demonstration program that was designed to improve access to hospital and other health services for rural residents.

Sections 1820 and 1861(mm) of the Act, as amended by section 4201 of the Balanced Budget Act (BBA) of 1997, replaced the EACH/RPCH program with the Medicare Rural Hospital Flexibility Program (MRHFP), under which a qualifying facility can be designated as a CAH. CAHs participating in the MRHFP must meet the conditions for designation specified in the statute and, under section 1820(c)(2)(B)(i)(I) of the Act, must meet the CoPs located at 42 CFR part 485, subpart F. Among such requirements, a CAH must be located in a rural area (or an area treated as rural) and must be located more than a 35-mile drive (or in the case of mountainous terrain or in areas with only secondary roads available, more than a 15-mile drive) from a hospital or another CAH unless otherwise designated as a ''necessary provider'' prior to January 1, 2006.

The CoPs are organized according to the types of services a hospital may offer, and include specific requirements for each hospital service or department. The purposes of these conditions are to protect patient health and safety and to ensure that quality care is furnished to all patients in Medicare-participating hospitals. In accordance with Section 1864 of the Act, State surveyors assess hospital compliance with the conditions as part of the process of determining whether a hospital qualifies for a provider agreement under Medicare. However, under section 1865 of the Act, hospitals can elect to be reviewed instead by private accreditation organizations approved by CMS as having standards and survey procedures that are at least equivalent to those used by CMS and State surveyors. CMS-approved hospital accreditation programs include those of The Joint Commission (TJC), the American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP), and Det Norske Veritas Healthcare (DNV) (See 42 CFR part 488, Survey and Certification Procedures.).

II. Provisions of the Proposed Rule and Response to Comments

On October 24, 2011, we published a proposed rule entitled ''Reform of Hospital and Critical Access Hospital Conditions of Participation'' (76 FR 65891). The proposed rule identified several priority areas in the CoPs for both hospitals (42 CFR Part 482) and CAHs (42 CFR Part 485) and set forth revisions intended to eliminate or significantly reduce those instances where the CoPs are duplicative, unnecessary, and/or burdensome.

We received approximately 1,729 public comments in response to the proposed rule. Many comments were supportive; however, there were some commenters that opposed the proposed provisions. Approximately 1,100 of the comments were part of a write-in campaign from anesthesiologists that supported what they described as CMS' upholding of physician supervision requirements, but objected to what the letters described as an effort to replace physicians with nurses.

In general, the comments can be classified into roughly three categories: comments from hospitals, comments from physicians, and those from non-physician practitioners. Commenters representing the hospital industry, as well as accrediting organizations, expressed overwhelming support for the proposals and agreement with our efforts to bring the CoPs in line with current medical practice, eliminate burdensome and obsolete requirements, and provide hospitals with operational flexibility. Physician groups mostly disagreed with staffing proposals, and expressed disagreement with what they viewed as the Agency's endorsement of the replacement of physicians with nurses and non-physician practitioners. While commenters representing non-physician practitioners expressed support for most of the proposals, they urged us to go further with changes that they believe would allow them to practice to the full extent allowed under their respective State laws and regulations. In the following section, we provide a brief summary of the proposed provisions, followed by responses to public comments received on each issue. For a detailed discussion of the proposals, see the October 24, 2011 proposed rule (76 FR 65891).

A. Revisions To Allow Flexibility and Eliminate Burdensome CoPs

1. Governing Body (§ 482.12)

We proposed to revise and clarify the governing body requirement to reflect current hospital organizational structure, whereby multi-hospital systems have integrated their governing body functions to oversee care in a more efficient and effective manner. Specifically, we proposed to revise the introductory text of § 482.12 to state that ''There must be an effective governing body that is legally responsible for the conduct of the hospital.'' We noted that we would retain the current provision that requires the persons legally responsible for the conduct of the hospital to carry out the functions specified in part 482 of our regulations that pertain to the governing body if the hospital does not have an organized governing body.

Comment: Many commenters wrote in support of the CMS proposal to allow a single governing body for all hospitals within a multi-hospital system and they characterized the current requirement for a separate governing body for each hospital as redundant and obsolete. Several comments suggested the change would provide hospitals with greater flexibility and help them operate more efficiently and effectively. Others noted that the change would simplify governance and administrative processes. These commenters also suggested the change would enhance the continuity and consistency of policies and practices across all hospitals within a multi-hospital system. One commenter suggested the change might streamline the workflow for nurses. Many commenters also remarked that the proposal was appropriate given the more integrated organizational models adopted by many hospitals.

Some comments detailed the greater efficiencies and cost savings that would result, including savings in areas such as finance, human resources, information technology, and purchasing. Many commenters specifically remarked that the change would end the redundant and inefficient practice of multi-hospital systems' holding duplicative, separate meetings for each of the hospital boards.

Some comments stressed the advantages that a single governing body would have in terms of enhancing mutual accountability, interdependence and timely oversight. Commenters remarked that the single governing body structure could facilitate shared learning, promulgation of best practices and help hospitals standardize performance metrics and eliminate variances. Another commenter stated that its policy of allowing a single governing body for a multi-hospital system has not had an adverse impact on quality and safety.

Response: We agree with the commenters that this change will positively affect hospitals. With the addition of a few changes pertaining to board membership, discussed below, we are finalizing this proposal for a single governing body. We will be finalizing the proposed language that refers to a hospital, generally, and removing the language referring to the hospital ''as an institution.''

Comment: Several commenters requested that CMS specify in regulatory text that, ''hospital systems with more than one CMS Certification Number may have a single governing body.''

Response: While we agree with the commenters' intent, and we recognize that the language suggested was excerpted from the preamble text of our proposed rule, we are not making this change in regulatory text. Rather, we will address this clarification in forthcoming sub-regulatory guidance. Our decision against using the term ''CMS Certification Number'' in the final regulatory text is merely a precaution intended to provide flexibility, should the terminology be changed.

Comment: Several commenters requested that CMS take a stronger position in favor of hospitals' adoption of a single governing body for their multi-hospital systems. Specifically, these commenters asked CMS to expressly state that, ''multi-hospital systems can be effectively led by a single governing body.'' On the other hand, we received comments requesting that CMS expressly state that ''multiple

hospitals cannot be effectively governed by a single governing body'' and that ''each hospital, including hospitals in a multi-hospital system, should have its own governing body.'' Still other commenters asked CMS to reaffirm the important role of local sub-boards.

Response: While we believe that multi-hospital systems might gain important efficiencies and achieve significant progress in quality programs under the governance of a single governing body, we also agree that local sub-boards might be a valuable resource in hospital governance. We believe there is an important and essential symbiotic relationship that should exist between a hospital's governing body and its medical staff. The dynamics of this relationship generate critical checks and balances that serve to promote and protect patient health and safety. We believe that the ongoing, timely communication between a governing body and its medical staff is essential to the successful coordination and advancement of patient care, regardless of whether the adopted governance model is one of a single governing body for all hospitals in a multi-hospital system, one of a single governing body with local sub-boards at each hospital in the system, or one of a separate governing body for each hospital. The intent of the proposed revision was to provide hospitals with some regulatory flexibility with regard to hospital governance and to acknowledge that alternative methods of governance exist that might prove as effective as the traditional methods currently required by the CoP. When practically applied in the ''real world'' of hospitals, each model of hospital governance has the potential to be flawed and dysfunctional just as each has the potential to be engaged and effective. We remind the commenters that the proposed revision to this requirement is an option that each multi-hospital system is free to choose or not to choose for itself. Because we have not seen sufficient evidence presented that would indicate that one model works more effectively than another, we do not believe that it would be appropriate for CMS to endorse one model of hospital governance over another.

Comment: Several of the commenters who expressed a clear preference for a hospital-specific governing body asked CMS to require that, at minimum, a member of the medical staff serve on the governing body. The commenters suggested that CMS' proposal to allow for a single governing body within a multi-hospital system would diminish communication and coordination between the governing body and the medical staff as it presently takes place at the individual hospital level. Commenters stated that an effective governing body needs to have an informed understanding of the care coordination challenges at each member hospital and that this can only be achieved when the lines of communication are open between the governing body and the medical staff.

To counter the potential disruption of communication that may be caused by the proposal to allow multi-hospital governing bodies, commenters suggested that CMS require that a member of the medical staff serve on the governing body. Commenters added that such a model would further inform patient health and safety initiatives within the hospital.

Commenters also expressed concern that, even under the current requirements which require a governing body at each institution, hospital physicians are generally not well represented on hospital governing bodies. Commenters stressed the importance of physician input at the governing body level, particularly as they believe it is essential in the context of CMS' proposal to permit a single governing body for a multi-hospital system.

Response: We agree with the commenters' suggestion, and we are modifying our final regulatory language to require that a hospital's governing body must include at least one medical staff member. We agree with the commenters that strong coordination between a hospital's governing body and medical staff is paramount to the delivery of quality care.

We note that these two, separate Conditions of Participation at § 482.12 (Governing body) and § 482.22 (Medical staff) have a long, overlapping, and interrelated history. In 1986, CMS discontinued a requirement for a joint committee to formalize liaison between the medical staff and the hospital's administration. At that time, we decided to leave decisions about liaison and coordination activities to internal hospital management (51 FR 22010, 22017, June 17, 1986). Because we are now making changes to the hospital's management structure by allowing a single governing body for multiple hospitals within a system, we believe that, in accordance with the comments we received on medical staff representation on the governing body, a formalized link between these interdependent entities is appropriate. While it may already be a requirement at some hospitals or simply a convention that others follow, we are not aware that this linked structure is the norm. We believe that adding the requirement for hospitals to have a medical staff member serve on the governing body will build in an important element of continuity and ensure regular communication between a hospital's governing body and its medical staff(s), particularly in light of our decision to permit a single governing body for hospitals in multi-hospital systems.

We also believe that requiring a hospital's governing body to include a medical staff member will directly address a widely voiced concern for stronger communication between a hospital governing body and the medical staffs of its member hospitals. In the case of a multi-hospital system with one governing body, we wish to clarify that we are not requiring that the governing body include a member of each separately certified hospital's medical staff, so long as at least one governing body member is a member of the medical staff of one system hospital. The governing body is free to select as many of its members from its medical staff(s) as it chooses. However, we would expect a multi-hospital system's single governing body to carefully consider the unique needs of the patient populations served by each of its member hospitals and their medical staffs when determining the number and composition of medical staff members to be appointed to the governing body. We recognize that physicians may be in a minority position on a hospital governing body even with this new requirement. That said, we believe that a physician who specifically represents medical staff members will hold some measure of enhanced standing within the governing body.

Comment: We received numerous comments opposing our proposal for a single governing body. Many of these comments came from State and national physician associations as well as from a number of community hospitals. In particular, comments opposing a single governing body expressed concern that such a structure would further weaken governing boards' understanding of the daily operations and medical staff affairs of each hospital and thereby lead to a reduction in both the quality of care and patient safety protections. One community health network reported that it had seen ''remote management'' lead to waste of resources in the healthcare delivery system.

Some commenters expressed particular concern about the implications that a single governing body would have in a hospital system comprised of diverse institutions. For example, commenters stated that a

single hospital system can encompass remote, rural areas as well as urban and suburban areas, and may also include specialty hospitals, such as a pediatric hospital. The commenters suggested that, if hospital systems like these moved to governance by a single, overarching governing body, a single body would not be able to properly address the needs of each separate hospital, particularly the needs of any hospital especially different from others in the system.

Some commenters suggested that a single governing body would be more appropriate to large hospital systems with similar hospital members and that CMS should pare back its proposal by only making the single body option available in certain cases, to be limited by geography or specialty.

A number of commenters opposed our proposal on the grounds that it could prove problematic for non-profit hospitals in light of the new requirements for these hospitals that are included in section 9007(a) of the Affordable Care Act (ACA). The commenters pointed out that this section of ACA revised section 501(r) of the Internal Revenue Code (26 U.S.C.A. § 501(r)) to require a non-profit hospital to establish and maintain their tax-exempt status by, among other things, conducting a community health needs assessment every three years. They stated that a non-profit hospital would not be able to conduct this required assessment through its own governing body (which they see as ''the natural convener of this activity in conjunction with the medical staff'') since they believe that our proposed governing body requirement, if finalized, may cause the hospital to lose its own governing body and be under the governance of a multi-hospital system's single governing body. The commenters also cited the requirements at § 501(c)(3) of the Internal Revenue Code regarding the tax-exempt status of non-profit hospitals and they stated that in order to meet the requirements of this section, a hospital must demonstrate that it provides a community benefit, which is defined by Internal Revenue Service (IRS) guidance as ''based on part on whether a wide range of members of the community have a seat on the governance board.'' The commenters stated that they believe ''CMS' proposal to allow a single governing body for a multi-hospital system that is divorced from the very community it is meant to represent'' would prevent these non-profit hospitals from meeting not only this IRS threshold for tax exemption, but also other State-specific requirements for tax-exempt status.

Response: We appreciate the concerns of the commenters. We do not believe that a multi-hospital system's governing body can properly function without its gathering information and input from the administrative and medical staff of each member hospital, or from the local sub-boards if the system utilizes this model for hospital governance. We note that the regulations, as finalized here, are intended to provide multi-hospital systems with an option, but not a requirement, to use a single governing body. In those instances where a system believes that its interests are best served by using a single governing body, under the new CMS regulations, that system will have the flexibility to do so, just as another multi-hospital system will have the flexibility to continue following the current requirement for a separate governing body for each hospital in its system if it determines that course would best serve its interests.

Comment: Several commenters asked CMS for clarity as to how a single governing body would operate within a multi-hospital system spanning different States.

Response: We would expect multi-hospital systems to follow the laws, regulations, and local ordinances of the States in which each member hospital operates. A hospital system's adoption of a single governing body, as permitted under this revised federal regulation, would not in any way preempt any relevant State requirements. Hospitals must continue to comply with all applicable State and local laws.

Comment: We also received a number of comments that asked how the new option for a single governing body would be implemented. One commenter asked how this would work for a multi-hospital system composed of more than one corporate entity. Another commenter asked whether survey decisions at each member hospital would be independent and whether this would impact the status of separately licensed, separately participating member hospitals in the system. Another commenter inquired about the integration of CAHs within a multi-hospital system, asking whether the proposal would allow for a system with both CAHs and hospitals to have one governing body or for systems with differing payment structures. Finally, we were asked to clarify between the CMS governance standard at § 482.12 and the requirements pertaining to co-located hospitals.

Response: We note that permitting a single governing body for multiple hospitals in a system does not relieve each separately certified hospital from the obligation to separately demonstrate its compliance with all of the hospital CoPs. Each separately certified hospital will continue to be separately, independently assessed for its compliance, through either State Survey Agency or approved national accreditation program surveys. Several of the commenters' statements suggested that there may have been some confusion around this point.

We offer hospital facilities considerable flexibility regarding how and whether they choose to participate in the Medicare program. Based on the geographic and other institutional limitations set out in our ''provider-based'' regulation at § 413.65, which addresses provider-based status for hospital facilities in multiple locations, hospital governing bodies make business decisions about how they want to participate in Medicare, and they indicate on their Medicare enrollment application the choices they have made. It is not uncommon to find multiple hospital campuses with one owner located in the same general geographic area enrolled in Medicare as one hospital. It also is not uncommon to see a hospital system choosing to enroll its various facilities as separate hospitals, even where their geographic proximity would permit them to be enrolled as one hospital. We are aware that various factors enter into consideration when governing bodies make these business decisions. For example, some governing bodies prefer to enroll various campuses as separate hospitals, out of a concern that problems at one hospital's campus might jeopardize the Medicare participation of the other campuses if they were a multi-campus hospital covered under one Medicare provider agreement. In other cases, a governing body may see the benefits of integrating medical and nursing staff of multiple campuses into one integrated hospital. In still other cases, the deciding factor might be the implications for Medicare reimbursement of graduate medical education, the ease of adding satellite locations, etc. We defer to the governing bodies of hospitals to weigh the pertinent factors, the permissible options, and to make business decisions in their best interests when applying to participate in Medicare.

Our hospital certification decisions and issuance of a provider agreement and CMS Certification Number (CCN) follow from these business decisions by a hospital's governing body. We often certify as one ''hospital'' entities whose locations are identified on the application as one primary location and one or more ''provider-based'' satellite locations, and issue one provider agreement to that hospital. Once so

certified, the resulting ''hospital'' must then separately demonstrate its compliance with the hospital CoPs, independent of any other facility. While a system consisting of multiple, separately certified hospitals with a single governing body may promote similar, or even identical, compliance policies across its separately certified member hospitals, it must make clear which hospitals the policies apply to, and each separately certified hospital is accountable for implementing the applicable policies, including securing the policy approvals of its separate medical staff where required under the regulations. As an example, we could envision a hospital system with a single governing body establishing a uniform approach to developing hospital quality assessment and performance improvement (QAPI) programs. The system might even choose to measure some common quality indicators and pursue similar performance improvement activities and projects across its member hospitals. However, each member hospital would be responsible for maintaining and making available to us evidence of its hospital-specific QAPI program; presentation of only system-level information would not be acceptable.

With respect to the commenter's statement about separate licensure, we are unclear as to what clarification the commenter is seeking, but we note that § 413.65(d)(1) addresses State licensure requirements in order for facilities to be provider-based to a hospital's main campus. Those regulations provide for flexibility where separate licenses are required under State law.

A CAH must be separately evaluated for its compliance with the CAH CoPs found in 42 CFR Part 485, Subpart F. It would not be possible to evaluate the CAH's compliance as part of an evaluation of a hospital's compliance. However, this does not preclude a multi-hospital system's single governing body from also serving as the CAH's governing body, so long as the governing body clearly identifies the policies and decisions that are applicable to the CAH.

We recognize the importance of these inquiries and will address these in more detail in forthcoming interpretive guidance (IG) after the publication of this final rule.

2. Patient's Rights (§ 482.13)

Section 482.13(g) requires hospitals to report deaths associated with the use of seclusion or restraint. We proposed to modify the reporting requirements for hospitals when the circumstances of a patient's death involve only the use of soft two-point wrist restraints and no use of seclusion. At § 482.13(g)(2), we proposed that hospitals would be required to report to CMS the type of deaths described here (those involving soft two-point wrist restraints and no use of seclusion) by having hospital staff record the information about the death into a log or other system. At § 482.13(g)(4), we proposed that each entry in the record must be made no later than seven days after the date of death of the patient and that the record must include the patient's name, date of birth, date of death, attending physician, primary diagnosis(es), and medical record number. We also proposed that hospitals must make this information available to CMS in either written or electronic form immediately upon request.

For deaths involving all other types of restraints and all forms of seclusion, we noted that we would retain the current, more extensive death reporting requirements to CMS by telephone no later than the close of business on the next business day following knowledge of the patient's death. In addition to reporting the deaths by telephone, we proposed to revise § 482.13(g)(1) to provide additional reporting options, which would include the use of facsimile and electronic reporting.

Comment: Many commenters favored the proposal to modify the reporting requirements for hospitals when the circumstances of a patient's death involve only the use of soft two-point wrist restraints. The favorable comments included those received from individual clinical professionals, hospitals and hospital associations, large healthcare systems, and several nursing groups. Several other commenters agreed with the revisions but recommended that the required logs be made publicly available.

Response: We appreciate the comments supporting the proposed change and the comments that suggested we add additional requirements and oversight. Changing the current reporting requirement to one that requires hospital staff to enter information into a log or other system those patient deaths that involve the use of only soft two-point wrist restraints will reduce unnecessary burden without negatively impacting patient safety. We believe the change will represent a welcome reduction in burden for hospitals and their staff, particularly in settings with a large number of patients in intensive care.

We disagree with adding new requirements for hospitals to publicize the details from the log (or other system). The log will contain protected health information from the patient's medical record, such as the patient's name, date of birth, and primary diagnosis, all of which are protected by the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule found at 45 CFR part 160 and part 164, subparts A and E. To further clarify that the method of reporting these deaths will be a hospital's maintenance of a log (or other system), to which a hospital must make an entry no later than seven days after an applicable patient's death, we are adding the word ''internal'' preceding ''log or other system'' in this final rule. We believe that this will clarify and emphasize that the log, or system that a hospital chooses to utilize for its reporting of these types of deaths, is one that will be maintained internally by the hospital and that CMS is not requiring public release of information about such deaths nor are we requiring hospitals to submit the information in the internal log (or other system) to CMS. However, in this final rule, hospitals will be required to make the information contained in the internal log or other system immediately available to CMS upon request as was initially proposed.

As discussed below, it is also important to remember that not all deaths of patients who die while in restraints, or shortly after their removal, are associated with the use of restraints. This is especially true in the context of soft two-point wrist restraints, which we note are often applied to acutely ill and medically unstable patients, prior to their eventual death, in order to prevent inadvertent patient removal of life-sustaining devices such as central lines and endotracheal tubes. The use of restraints in these cases is incidental to the patient's death and is not the cause of that death. Therefore, we do not believe that making public the information in the internal log (or other system) would contribute to ongoing quality improvement efforts.

Comment: Some commenters wanted CMS to require hospitals to make the data available to protection and advocacy (P&A) agencies and to report the deaths to P&As as well as to CMS using a log or other system, as set forth at proposed § 482.13(g)(4). A few commenters called for CMS to require hospitals to provide P&As access to the hospitals' logs specifically in accordance with applicable federal and State laws. Some commenters further requested that CMS create an explicit reference in § 482.13 to the Developmental Disabilities Assistance and Bill of Rights Act of 2000, particularly with respect to the role of P&A agencies and their access to

information concerning the deaths of disabled individuals.

Many commenters urged CMS to continue working to prevent future deaths by improving the data collection and analysis of restraint- and seclusion-related deaths, including those reported using the log or other system.

Response: We believe that data collection and analysis will be greatly improved by making changes to the way hospitals report data to CMS, and, at this time, we do not believe that expanding the requirements beyond what we have proposed would improve patient safety.

We are always looking for ways to improve and to increase the efficiency of communication that already occurs between CMS and P&As. We believe that the current, extensive reporting requirements may have impeded data collection and analysis. Adjusting the reporting requirements for a significant subset of restraint-related deaths, where only soft, two-point wrist restraints were used, will help to streamline data collection and sharpen our analytical focus.

Finally, we decline the commenters' request for an explicit reference to the Developmental Disabilities Assistance and Bill of Rights Act, as we believe such a reference is inappropriate in § 482.13. We note that the Conditions of Participation at § 482.11(a) already requires compliance with applicable Federal laws related to health and safety of patients, and we expect hospitals to ensure that any such requirements are met. However, as a practical matter, we must stress that CMS does not enforce other agencies' laws or rules, as would be the case with the above-referenced statute. CMS would only cite the facility for noncompliance with the aforementioned CoP at § 482.11 if the agency having jurisdiction makes a final determination that there was a violation.

Comment: Some commenters requested that CMS expand the proposed reporting requirements at § 482.13(g)(4)(ii) by requiring hospitals to also record the length of time the patient was kept in the restraints as well as the reasons for and consequences of the restraint use.

Response: We are requiring that hospitals document the patient's primary diagnoses along with the medical record number and other details. We believe that the data recorded in the internal logs will be sufficiently rich to conduct analysis of deaths where only soft, two-point wrist restraints were used. We do not believe that additional descriptions around the use of the restraints are necessary at this time. As we have stated elsewhere in this discussion and in our proposed rule, we are not aware of any research—or even any anecdotal information—suggesting a cause-and-effect relationship between the use of soft, two-point wrist restraints and patient deaths.

Comment: Some commenters suggested flexibility in reporting the deaths involving soft two-point restraints. They recommended that we allow for fax and electronic reporting of soft two-point restraint deaths.

Response: We proposed that hospitals must maintain a log or other system of deaths involving only soft two-point restraints that can be made available to CMS immediately upon request, and that the required information about these deaths must be entered into the log no later than seven days after the date of the death of the patient. The words ''log or other system'' at § 482.13(g)(2) were chosen to create flexibility, such that a hospital could adopt a written or electronic means of tracking these deaths. However, since we did not propose to require hospitals to submit these reports to CMS, except upon request, we wish to clarify that routine faxing and electronic reporting of the deaths at § 482.13(g)(2) directly to CMS is not necessary. Finally, we would note that the regulatory text now adds significant flexibility to the reporting options at § 482.13(g)(1) for all other deaths, permitting such reports to be made ''by telephone, facsimile, or electronically, as determined by CMS.''

Comment: One commenter recommended that we revise the overall requirement for death reporting in this rule. Two other commenters stated that the reporting requirements should be in accordance with State law. One commenter stated that reporting all deaths of patients who were restrained does not produce an accurate number of deaths caused by restraints. The commenter also noted that some patients may be near death when they are put into restraints and recommended that we clarify in the final rule that these individuals should not be included in the reporting requirement.

Response: The requirements for reporting deaths of persons who were placed in restraints and/or seclusion were established by section 3207 of the Children's Health Act of 2000 (Pub. L. 106–310, codified as section 592 of the Public Health Service Act (42 U.S.C.A. 290ii–1). Eliminating all reporting for this class of restraint deaths and relying on State law would be contrary to federal law, which requires hospitals and many other categories of healthcare facilities to report all restraint-related deaths. As stated in the proposed rule, we believe that a regulation requiring hospital staff to record information regarding the patient death into a log or other system (and which is made available to CMS immediately upon request) is entirely appropriate for these types of patient deaths and that it will satisfy this requirement for reporting deaths involving soft two-point restraints.

Regarding which restraint deaths that should be reported, we agree that not all deaths that occur while a patient is restrained are proximately caused by the restraints themselves, and we have proposed these revisions so as to reflect this fact (revising the reporting requirements for soft two-point restraints). In proposing this revision, we looked at all death reporting that is required of Medicare-participating hospitals. For deaths involving all other types of restraints and all forms of seclusion, we are retaining the current reporting requirements. We proposed to add flexibility to those requirements by allowing the reports to be faxed or submitted electronically.

However, as we reviewed the public comments regarding these proposed revisions, it became apparent to us that our proposed language might still cause some confusion regarding which restraint deaths truly must be reported to CMS through the ongoing submission of data and which restraint deaths can be reported by recording the information in an internal log or other system that the hospital would make immediately available to CMS upon request. We came to the conclusion that the proposed regulatory language was still not sufficiently clear. We learned that, due to our use of the phrase ''report to CMS'' in proposed § 482.13(g)(2), many hospitals assumed that they would still be required to report the information through submission of data to CMS for those deaths related to soft, two-point wrist restraints. This was not our intention and does not achieve our purpose of reducing unnecessary regulatory burden. Therefore, in this final rule we have revised the proposed language to delete the phrase, ''report to CMS,'' and now will require that for those deaths related only to soft, two-point wrist restraints the hospital staff must record the information regarding the patient's death in an internal log or other system. We are finalizing as proposed the requirement that this information must be entered no later than seven days after the death and that the information in the internal log or other system must be made available to CMS immediately upon request in either written or

electronic form. We are also finalizing the requirement that each entry must document the patient's name, date of birth, date of death, name of attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c), medical record number, and primary diagnosis(es).

Additionally, and in order to maintain consistency with these changes, we are revising the regulatory language proposed at § 482.13(g)(3). The language finalized here revises paragraph (g)(3) to contain two separate provisions and will now require that hospital staff must document in the patient's medical record the date and time the death was: (1) Reported to CMS for deaths described in paragraph (g)(1) or (2) recorded in the internal log or other system for deaths described in paragraph (g)(2).

Comment: Some commenters recommended that we have a common reporting system. They stated that all deaths should be reported consistently, in the same manner and within the same timeframe, by the close of the following business day. They stated that having two separate reporting mechanisms would be confusing and would upset the existing, well-established uniform reporting protocols.

Some commenters quoted our responses in the 2006 final rule on Patient's Rights where we said ''a uniform definition of restraint across care settings is a good approach, adds clarity, and avoids confusion * * * This definition renders unnecessary the otherwise impossible task of naming each device and practices that can inhibit a patient's movement'' (71 FR 71388). These commenters suggested the CMS was disrupting this uniformity with the new revisions contained in this final rule.

Another commenter suggested that the new requirement for an internal log or other system would be more burdensome than the present requirements for reporting the death to CMS by telephone. The commenter wondered whether the new requirements would mean the maintenance of a separate log by an assigned individual to research the patient's medical records to obtain all the necessary information. Another commenter asked whether the new requirement for an internal log would include hospital databases where reports could be generated and sent to CMS.

Response: We believe that the commenters have taken the responses to comments in the 2006 final rule out of the context in which they were discussed, that is, a uniform definition of restraint. For the sake of clarity, we note that we have not made a change to the definition of ''restraint.'' We still maintain that ''a uniform definition of restraint across care settings'' is the best approach and we are not changing that in this rule. What we are finalizing is a change to the reporting requirements and not to the definition of restraint. We have received extensive feedback from those who would be implementing the new reporting requirements, and this feedback has largely been favorable.

We believe the new requirements will relieve some burden on hospitals and their resources. We already expect hospitals to be tracking the details of deaths where the patient had been restrained by soft, two-point wrist restraints. Under the new requirements, this information will no longer need to be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death.

As suggested by one commenter, the requirements for the internal log or other system could be satisfied by the maintenance of a database where reports could quickly be generated if requested by CMS.

Comment: One commenter asked why a death that could be related to soft wrist restraints calls for less accountability and why a hospital could take a week to report the death.

Response: Hospitals remain accountable for the appropriate medical treatment of their patients and for all deaths that occur in their facilities. Not all circumstances involving restraints and associated deaths are the same. As discussed in the proposed rule, critically ill patients are often restrained in soft two-point restraints to prevent them from removing life-saving tubes and lines. And as we have stated elsewhere in this discussion and in our proposed rule, we are not aware of any research—or even any anecdotal information—suggesting a cause-and-effect relationship between the use of soft, two-point wrist restraints and patient deaths. Since such deaths are incidental to the use of these types of restraint, we believe that the revised reporting requirements that we are finalizing here are appropriate to the goal of ensuring hospital accountability for patient safety without continuing to impose undue regulatory burden in these instances.

Regarding the 7-day timeframe for documenting the entry about this type of patient death that we are finalizing in this rule, this modification affects only that segment of patient deaths where no seclusion is used and the only restraints used are soft, two-point wrist restraints. Even though this rule will allow for this timeframe, which we believe is entirely appropriate for those deaths where the use of restraints is incidental and not the cause of the patient's death, we do not expect a hospital to take the full seven days to document the entry on each of these deaths into its internal log or other system. Since the provision requires a hospital to provide the information in its internal log or other system to CMS immediately upon request, we would expect a hospital to enter the information as soon as possible in order to ensure that it has the most up-to-date information on these patient deaths in its system. However, to continue to require hospitals to report the deaths of these patients by the end of the next business day requires a significant amount of effort, and does not improve patient safety. Therefore, we are finalizing the 7-day timeframe requirement for documenting the entry in the log or other system as proposed.

Comment: One commenter recommended that we require hospitals to retain the death reporting log for at least six years.

Response: We disagree with requiring hospitals to retain the internal log for a minimum of six years, which, we note, is longer than the current requirements for medical records. However, State law may require longer periods of record retention for patient medical records or documents.

Comment: Several commenters stated that having a time frame longer than 24 hours to submit information may be more effective at reducing burden than having two separate methods and timeframes. Still other commenters stated that having a longer timeframe to submit a report will not decrease burden.

Response: We disagree with both comments. We believe that the proposed revisions to the death reporting requirement will provide flexibility to eliminate burden while ensuring patient safety. And we point out that the provision we are finalizing does not require the submission of information for the deaths related to soft, two-point wrist restraints only; the revised provision requires only the recording of information about these types of deaths in an internal log or other system.

Comment: A commenter asked CMS to consider setting minimum timeframes for both the renewal of a restraint order and the monitoring of those patients in restraints who are non-violent or non-self destructive. The commenter suggested that undefined timeframes could exacerbate situations already

lacking in the practice of re-evaluations for continued restraint. The commenter also suggested that the absence of set timeframes contributes to problems concerning quality of care and patient autonomy and harms altruistic efforts, generally. The commenter stated that extended periods of restraint and seclusion pose a serious safety issue for non-violent or non-self-destructive patients, including those in vulnerable populations, and advocated for greater standardization in the guidelines.

Response: These comments are outside the scope of this rule. While we thank the commenter for his or her opinions on this matter, we have not seen any evidence that such requirements for these types of orders improve patient safety. We believe that establishing arbitrary minimum timeframes for the renewal of orders for both restraints and subsequent monitoring of non-violent, non-self destructive patients could impede a hospital's flexibility in establishing its own policies and procedures for these orders, based on what the hospital knows would best meet the needs of its specific patient populations. Additionally, timeframe requirements could also increase provider burden in this area if the CMS timeframes are more restrictive than a hospital's current practice.

Comment: One commenter requested that CMS make a clarifying statement regarding the requirements at § 482.13(e)(5) that would identify which practitioners may order restraint or seclusion. The commenter noted that the current requirements use the term ''licensed independent practitioner'' and that this has been interpreted by many to mean that a physician assistant may not order restraint and/or seclusion. The commenter expressed disagreement with these interpretations and suggested instead that, where permitted by State law, a physician could delegate the ordering of such measures to a physician assistant. The commenter requested that CMS provide a clarifying statement that (1) PAs are authorized to order restraint and seclusion and (2) are subject to training requirements.

Response: The commenter is correct in pointing out that the current requirements use the term ''licensed independent practitioner.'' According to the State Operations Manual (SOM), the IGs for § 482.13(e)(5) state, ''For the purpose of ordering restraint or seclusion, an LIP is any practitioner permitted by State law and hospital policy as having the authority to independently order restraints or seclusion for patients.'' Therefore, if an individual PA was authorized by State law and hospital policy to independently order restraints or seclusion for patients, then that PA could do so within the hospital. However, since PAs have traditionally defined themselves as ''physician-dependent'' practitioners (as opposed to APRNs, who see themselves as independent practitioners), it is unlikely that a PA would be authorized by State law and hospital policy to ''independently'' order restraints or seclusions for patients as would be likely for licensed independent practitioners such as physicians, APRNs, and clinical psychologists. The supervising physician-PA team concept (and PA practice dependence on the supervising physician) is supported by the American Academy of Physician Assistants' description of the PA profession: ''Physician assistants are health professionals licensed or, in the case of those employed by the federal government, credentialed to practice medicine with physician supervision'' (American Academy of Physician Assistants. (2009–2010). Policy Manual. Alexandria, VA.). Moreover, a PA would not be allowed to order restraints or seclusion if the only authority to do so was delegated by a physician since this physician-delegated authority would establish that the PA was not independently authorized by State law and hospital policy, which we stated is a prerequisite for this type of order.

PAs (and RNs) are subject to the training requirements in this section, in addition to any special requirements specified by hospital policy associated with the one-hour face-to-face evaluation of a patient who is restrained or secluded for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.

Comment: One commenter inquired whether a ''geri chair'' is considered a restraint that would require reporting according to the revised requirements.

Response: The only reporting change we proposed concerns those deaths where no seclusion has been used and the only restraints used were soft two-point wrist restraints, as set forth at § 482.13(g)(2). Per current IG for § 482.13(e)(1)(i)(A), found in the SOM (*http://cms.hhs.gov/manuals/Downloads/som107ap_a_hospitals.pdf*), a geri chair or a recliner could meet the definition of restraint only if the patient cannot easily remove the restraint appliance and get out of the chair on his or her own.

Comment: One commenter inquired whether certain new types of restraints would be considered to fall within the ''soft'' two-point wrist restraint subset. The commenter described the material as made of nylon and a foam type of material, rather than the more commonly used cotton and wool materials, and that Velcro would be used to fasten them. The commenter also asked why CMS did not explicitly mention soft restraints which were applied to the ankles rather than a patient's wrists.

Response: We would not expect hospitals to change their reporting method for deaths involving any restraints that could be described as hard and rigid, such as leather restraints.

CMS has specifically revised the reporting requirements for soft two-point restraints that are used only on the wrists and not those that were applied to a patient's ankles or elsewhere on the body.

We wish to stress that the restraints we are setting out for documenting in an internal log are those typically used in critical care settings, such as intensive care units, where such restraints are medically necessary. Soft two-point wrist restraints are commonly used to prevent patients from removing medically necessary devices and equipment such as central lines, endotracheal tubes, and nasogastric tubes.

Comment: One commenter referenced a 2006 report, ''Hospital Reporting of Deaths Related to Restraint and Seclusion,'' published by the DHHS Office of Inspector General which found communications lapses among CMS, the Food and Drug Administration (FDA)—which monitors deaths associated with a medical device, Protection and Advocacy Agencies (P&As), and State survey agencies working on behalf of CMS. The commenter expressed concern about the OIG's findings, including its documenting of significant underreporting to CMS by hospitals of restraint- or seclusion-related deaths, as well as delays in reporting. The commenter inquired whether reporting delays had diminished since the report's publication.

Response: We have limited data, but we believe that the current reporting requirements may actually exacerbate hospital underreporting or untimely reporting of deaths associated with restraint or seclusion. A review of data collected on deaths reported in May and in December of 2007 indicated that only 13.5 percent of all types of hospitals nationally had submitted any reports during those two months. Between 2008 and 2010 our Regional Offices entered into our survey and certification

database a sampling of reports, taking reports from two or three months in each of the years. We analyzed the data and found results consistent with a pattern of underreporting. At least for IPPS hospitals, which provide short-term acute care hospital services, and where soft wrist restraints are often used in critical care settings when patients are sedated and restrained for their own safety in order to preclude patient removal of items such as endotrachial tubes and central lines, we would have expected every such hospital to have had one or more cases per month of a patient who died while two-point soft wrist restraints were in use, or shortly thereafter. In fact, we received at least one report from only 41 percent of all IPPS and psychiatric hospitals during the sampled periods between 2008 and the present. Underreporting has proven to be an ongoing challenge under the current rule.

We would also note that, since the great majority of death reports that hospitals do submit involve two-point soft wrist restraints only, most of the reports submitted to us are reviewed and filed without any further action, since we do not believe in such cases that the use of the two-point soft wrist restraint contributed to the patient's death. In such cases we believe it would not be an effective use of our limited survey resources to conduct an on-site investigation as a follow-up to a death report where only soft two-point wrist restraints had been used and where there was no evidence that the death was caused by the restraints used. It is not surprising that many hospitals might fail to perceive a linkage between the use of a two-point soft wrist restraint and a patient's death, and therefore the need to report such deaths to us as a death associated with the use of restraint or seclusion. We believe the revised reporting requirement will enhance patient safety by only requiring the prompt submission to us of a more narrow range of patient deaths where the likelihood of causation by the use of restraint or seclusion is greater. We also believe we will be able to address underreporting more effectively under the revised rule. We also believe the new regulatory requirement will better focus hospitals' attention and corrective efforts in these riskier areas.

Comment: A commenter remarked that, in proposing the changes to reporting by hospitals, CMS did not discuss the data from deaths related to other types of restraints or seclusion.

Response: We agree with the commenter's apparent suggestion that more study may be necessary to evaluate the impact from other types of restraints or seclusion. As in the drafting of this proposal, CMS has pursued a conservative, cautious approach before finalizing the new requirements. In the proposal, we stated at the onset that, ''CMS is not aware of any research—or even any anecdotal information—suggesting a cause-and-effect relationship between the use of soft, two-point wrist restraints and patient deaths.'' As discussed above, in the context of the 2006 OIG report, ''Hospital Reporting of Deaths Related to Restraint and Seclusion,'' CMS has found this subset of restraint-related deaths to represent a substantial percentage of reported deaths to CMS. We do not believe there is a causal relationship between the use of soft two-point wrist restraints and patient deaths. Moreover, no public comments were submitted that provided any evidence or research to the contrary. We believe the new reporting requirements will allow CMS to focus more closely on data from deaths related to other types of restraints or seclusion where there is a greater likelihood of finding harm due to the restraints or seclusion.

Comment: A commenter suggested that CMS should add language limiting its proposed change in the reporting requirements to the use of 2-point soft wrist restraints ''in intensive and critical care units'' and ''to prevent patients from removing medically necessary devices and equipment restraints.''

Response: We believe that the revised reporting requirements are appropriate and that the commenter's suggested additions could be problematic. We agree that soft two-point wrist restraints are generally used in intensive and critical care units and that they are used to prevent patients from removing medically necessary devices and equipment restraints. However, we would not expect hospitals to limit the use of such restraints to intensive and critical care units alone.

Comment: A commenter suggested that CMS change its proposed language to be more inclusive of non-physician providers. The commenter recommended that § 482.13 (g)(4)(ii) be re-worded to read: Each entry must document the patient's name, date of birth, date of death, attending physician ''or other clinician's'' name, medical record number, and primary diagnoses.

Response: We appreciate the commenter's suggestion. We agree that the proposed regulatory text does not take into consideration that patients who are not Medicare patients may be under the care of a non-physician practitioner or licensed independent practitioner, as that term is used here, if allowed under State law and hospital policy. Therefore, we are making a change to the regulatory text at § 482.13(g)(4)(ii) so that it will now read, ''name of attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 481.12(c).'' This will make the regulatory text here consistent with other provisions in this section. For Medicare patients, the requirements of § 482.12(c) will still apply.

3. Medical Staff (§ 482.22)

The CMS CoP on ''Medical staff,'' at § 482.22, concerns the organization and accountability of the hospital medical staff. We proposed three revisions to the Medical staff CoP.

First, we proposed to redesignate § 482.22(a)(2) as § 482.22(a)(5) and revise it by adding language to clarify that a hospital may grant privileges to both physicians and non-physicians to practice within their State's scope-of-practice law, regardless of whether they are also appointed to the hospital's medical staff. That is, technical membership in a hospital's medical staff would not be a prerequisite for a hospital's governing body to grant practice privileges to practitioners. Second, we also proposed to require that those physicians and non-physicians, that have been granted practice privileges within their scope of practice, but without appointment to the medical staff, are subject to the requirements contained within this section.

The third area in which we are proposing changes concerns the more direct responsibilities for the organization and accountability of the medical staff. These requirements are set forth at § 482.22(b)(3). Presently, the hospital may assign these management tasks to either an individual doctor of medicine or osteopathy or, when permitted by the State in which the hospital is located, a doctor of dental surgery or dental medicine. We proposed to allow a hospital the option of also assigning the leadership of the medical staff to a doctor of podiatric medicine when permitted by the State law of the State in which the hospital is located.

Comment: Overall, the majority of comments were overwhelmingly supportive of the proposed changes to the Medical staff CoP at § 482.22(a) that would broaden the concept of ''medical staff'' to include other practitioners who are granted hospital privileges to practice in the hospital in accordance with State law, not only those who are actually appointed to sit on the medical staff. However, a significant number of

commenters, while supportive of the proposed changes, recommended that CMS go further with its revisions in this area. Specifically, they would like to see the requirements finalized with these additional revisions incorporated into the regulatory text:

- Medical staffs must be representative of all types of health professionals who have privileges, including Advanced Practice Registered Nurses (APRNs) and Certified Nurse Midwives/Certified Midwives (CNMs/CMs), and who provide services to a hospital's patients, and as they are authorized to provide services under State law and to the extent of their full scope of practice;
- Non-physician members of the medical staff must be accorded the same rights and protections as physician members, including full voting privileges, membership on committees, ability to appeal, and due process;
- The credentialing and privileging process and the selection process for medical staff membership must be transparent and follow established criteria;
- Each application for privileges must be completely reviewed and a determination made within a 60-day period; and
- The applicant must be notified of the determination in writing with an explanation of the determination.

One commenter asked for the ''specific inclusion of registered dieticians as non-physician practitioners included and affected by the proposed regulation.'' Another commenter voiced support for the proposal to allow hospitals to grant privileges to non-physicians, regardless of whether they are also appointed to the hospital's medical staff, but believed that expressly limiting the non-physician practitioner's scope of practice to what is allowed by the State in which the hospital is located (as we have proposed here) has the potential to greatly limit the value to be gained from that practitioner. The commenter stated further that it is well documented that more than half of the States have implemented regulations and restrictions that impede the full realization of the potential of APRNs, and that the quality of care by APRNs does not vary by State. The commenter affirmed that APRN care is of the same quality as that provided by physicians for the same services, and that there is no clinical reason for these variations in State scopes of practice. Finally, this commenter urged CMS to establish a standard that recognizes non-physician practitioners should be privileged to practice to the full extent of their professional education and capabilities by deleting the reference to State licensing in the proposed requirements. The commenter believes that this would be a way to break down unwarranted barriers to full utilization of APRNs and other non-physician practitioners in hospitals and that such a change in the final rule would be consistent with recommendations in *The Future of Nursing: Leading Change, Advancing Health* (Institute of Medicine, October 2010). It should be noted here that many of the other commenters who asked for CMS to go further in the revisions to the medical staff requirements also cited this IOM report. The IOM report includes a recommendation specific to CMS, which urges that we amend or clarify our requirements to ensure that advanced practice registered nurses are eligible for clinical privileges, admitting privileges, and membership on medical staff.

Conversely, we also received a significant number of comments from those who were adamantly opposed to the proposed changes. A majority of the dissenting opinions took the form of comments expressing serious concerns about allowing non-physician practitioners to obtain hospital privileges without becoming members of the medical staff. These commenters continued by stating that, ''allowing some providers to circumvent medical staff oversight will detrimentally impact patient safety and quality afforded to Medicare beneficiaries and all patients.''

Many of the comments opposed to the proposed changes specifically focused on the proposal to allow physicians to be granted hospital practice privileges without requiring them to be appointed to the medical staff. The commenters stated that this proposed change would allow a hospital to exclude certain physicians from the medical staff, would effectively divide a hospital's physicians into two groups (those on the medical staff and those who are not), and would undermine what the commenters see as the medical staff's chief function: self-governance. The commenters maintain that appointment to the medical staff provides a physician with a voice in the governance of the medical staff and patient care, including the specific needs of that physician's patient population. Further, the commenters stated that the medical staff appointment ''engenders a mutual responsibility for the activities and work of the medical staff—such as quality improvement—promoting a mutual objective to oversee and protect the health and safety of patients.'' The commenters believe that this mutual objective of the medical staff is responsible for both professional standards and patient care.

These same commenters believe that the proposed changes would allow hospitals to circumvent the protections that the medical staff bylaws provide for physicians (for example, judicial enforcement of any procedural rights contained in the bylaws). The commenters state that the changes ''could allow hospitals to avoid lawsuits by physicians who would otherwise be protected by the contractual relationship created by virtue of their appointment to the medical staff.'' In other words, the commenters believe that the protections afforded to physicians by the medical staff bylaws are only available to those physicians who are appointed to the medical staff and that merely being granted clinical privileges to practice is not enough to guarantee these protections.

The commenters also voiced concern over what they saw in the proposed rule as an opportunity for hospitals to privilege physicians outside the authority of the medical staff. In their comments, they state that they are opposed to our proposal to allow a governing body to grant privileges in accordance with ''hospital policies and procedures,'' and not upon the recommendations of the medical staff ''in accordance with medical staff bylaws, rules, and regulations,'' as is currently required in the regulations. They believe that, if allowed, this could have a negative impact on peer review of physicians in hospitals. The commenters expressed concern that those who are privileged but not appointed to the medical staff would not have the same due process protections of peer review accorded to members of the medical staff members. Commenters questioned whether these physicians would then be subject to a hospital-driven review process that is dictated only by a hospital's administration without any medical staff input or with input from only a few hospital-selected medical staff members. They also are concerned that a privileging process that is allowed to be un-tethered from the medical staff could lead to various fraudulent practices by hospitals to which the commenters are opposed. Examples cited by commenters include the practice of ''economic credentialing,'' which the commenters described as the use of economic criteria (for example, potential to generate the most revenue for the hospital based on increased referrals) unrelated to the quality of care or professional competence to determine a practitioner's qualifications for privileges, and ''horse trading,''

which they described as a practice whereby two or more hospitals informally agree on the privileging status of applicants based on the hospitals' mutual interests. The commenters requested clarification from CMS on all of these points and urged us to ensure that the proposed requirements would retain the authority of the medical staff, in accordance with its bylaws, rules, and regulations, to make medical staff appointment and privileging recommendations and that these changes would not hinder or obstruct medical staff peer review efforts. The commenters also encouraged CMS to look at the proposed regulatory language with regard to medical staff oversight of non-medical staff practitioners. They pointed out that there is no specific mention in the rule of the applicability of the medical staff bylaws and oversight to these types of practitioners, both physicians and non-physicians alike.

With regard to the discussion of non-physician practitioners and medical staff privileges in the proposed rule, these same commenters objected to what they saw as ''CMS's explicit endorsement of the replacement of physicians with non-physician practitioners throughout the rule.'' They commented that they believe that CMS's stated intent of the revisions to the medical staff CoP was to replace physicians with non-physicians, and this would be ''contrary to the purpose of the CoPs, namely, to provide a safe hospital setting.'' While the commenters recognized the value that non-physician practitioners provide to the healthcare team, they maintained that physicians are the practitioners who are best qualified to lead that team, particularly in a hospital setting where patients are treated for complex and critical illnesses and injuries. They further objected to what they saw in the proposed rule as CMS' explicit encouragement of the expansion of scope of practice laws by States. The commenters pointed out that this conflicts with the express regulatory language of the proposed rule, which defers to existing State scope of practice laws, and they cautioned that any expansion of these laws should be based on a review of the evidence and on the training and education of non-physician practitioners to determine if such expansions are truly in the best interests of patient health and safety.

Finally, the commenters urged CMS to consider their assertion that medical staff appointment and privileges are not ''either/or'' propositions. They pointed out that the American Medical Association (AMA) has long given its members guidance on medical staff categories of membership and cite the following examples: ''Active,'' ''affiliate,'' ''administrative,'' ''call coverage,'' ''telemedicine,'' and ''temporary'' (*Evolving Relationship between Hospitals and Medical Staff.* Brian M. Peters, Esq. (2001). AHLA Seminar Materials. Post & Schell, PC). They stated that while these categories ''differ in their level of responsibility and oversight,'' the categories do ''share the comity of membership in the medical staff, which we believe engenders a shared accountability.'' While the commenters noted that CMS mentions medical staff categories in the preamble, they point out that most medical staffs already employ categories and these are specified in the medical staff bylaws. Again, the commenters urged CMS to remove its proposed requirement at § 482.22 that would allow for the exclusion of some physicians from both the participation in, and the protections, of the medical staff.

Response: We appreciate the support for the proposed changes. We also thank the commenters for their recommendations to make additional revisions to the medical staff requirements that would allow APRNs and other non-physician practitioners to practice to the full extent of their education and training. We have also noted the recommendations of the IOM report regarding our requirements and the eligibility of APRNs for hospital privileges and medical staff membership.

Upon review of our proposed medical staff requirements and the public comments received, we realized that we might not have achieved what we originally intended with these changes, that is, to provide hospitals with the flexibility they would need to explore new approaches to care giving by allowing them the ability to increase the numbers and types of practitioners who could be granted hospital privileges to treat and care for patients. As we proposed in these revisions, any regulatory limits on these privileges would be imposed by the State licensing and scope-of-practice laws of the State in which the hospital is located. We sought to relieve regulatory burden by clarifying and revising the current requirements so that hospitals would still be allowed to appoint non-physician practitioners to their medical staffs, but that medical staff membership would not be a prerequisite to being granted privileges in the hospital, regardless of whether a practitioner was a physician or a non-physician. Based on the public comments received, we are revising our proposed Medical staff requirements in this final rule to better address the many valid issues that were raised by both those who supported this section of the proposed rule and those who opposed it.

While we agree with the IOM report's recommendation that we amend our requirements to ensure that advanced practice registered nurses are eligible for hospital privileges and membership on medical staff, we respectfully disagree with the commenters' suggestions that we need to add additional requirements that would guarantee both non-physician practitioner representation on the medical staff as well as specific rights for those non-physician practitioners. In addition, we also disagree with the recommendations offered in the comments that we add very specific and highly prescriptive requirements pertaining to a hospital's credentialing and privileging process. The current requirements already provide for a transparent process based on established criteria. Although the current requirements provide a level of specific guidance to hospitals and their medical staffs regarding the privileging and medical staff appointment process, we do not believe that there is sufficient evidence to indicate that a hospital medical staff and, subsequently, patient health and safety would benefit from the addition of more rigid and prescriptive provisions, such as the commenters' specific recommendations to require a 60-day timeframe for a hospital to review and determine privileges for an individual practitioner applicant, or to require that the hospital notify the practitioner applicant in writing with an explanation of its determination.

We also disagree with the one commenter's recommendation that we specifically include registered dieticians in the category of non-physician practitioners affected by this rule. We assume that the commenter means that hospitals should be required to recognize registered dieticians as members of their medical staffs. We point out that the final rule does not specifically name any category of non-physician practitioner in the regulatory text. While we frequently mentioned APRNs and PAs in our discussions regarding the composition of the medical staff in both the proposed and final rules, we have done this only because these categories of non-physician practitioners have scopes of practice within the hospital setting that are often second only to physicians in terms of how broad those scopes of practice are. For this reason, these categories of non-physician practitioners seem the most logical and

appropriate choices of categories eligible for appointment to a hospital's medical staff. The current requirements and the revisions contained in this rule are written to allow a hospital's governing body the greatest flexibility in determining which categories of non-physician practitioners that it chooses to be eligible for appointment to the medical staff. Once the hospital's governing body determines which categories are eligible for appointment, the new requirements in this final rule will ensure that the medical staff examines the credentials of all eligible candidates and that it makes its recommendations for medical staff appointments to the governing body in accordance with State law, including scope-of-practice laws, and the medical staff bylaws, rules, and regulations. The rule is intended to encourage hospitals to be inclusive when they determine which categories of non-physician practitioners will be eligible for appointment to their medical staff. Under the new requirements, an individual hospital would be allowed to include registered dieticians as a category of non-physician practitioners eligible for medical staff appointment as long as their inclusion is in accordance with the laws of the State in which the hospital is located.

We also respectfully disagree with the comments recommending that we use our rulemaking authority to recognize non-physician practitioner professional education and capabilities in our requirements by removing our deference to State licensing and scope of practice laws. As we stated in a recent rule addressing credentialing and privileging and telemedicine services, ''CMS recognizes that practitioner licensure laws and regulations have traditionally been, and continue to be, the provenance [sic] of individual States, and we are not seeking to pre-empt State authority in this matter. We believe that the proposed requirements regarding State licensure leave room for the laws that exist today as well as any changes to these laws that may occur in the future, including any increase in the number of States that decide to engage in compacts, privilege to practice or reciprocity agreements, endorsements, and other arrangements regarding practitioner licensure (76 FR 25557).'' We would also note that generally, federal agencies do not issue rules preempting State law unless Congress explicitly or implicitly requires such preemption. Therefore, we will continue to defer to individual State practitioner licensing and scope of practice laws with regard to hospital privileges and medical staff appointments.

Finally, we do not agree with commenters' assertion that our goal is to ''replace physicians with non-physicians.'' Our overall intent in revising the proposed requirements in this final rule continues to be what we initially expressed in the proposed rule, namely, to provide the flexibility that hospitals need under federal law to maximize their medical staff opportunities for all practitioners, particularly for non-physician practitioners, but within the regulatory boundaries of their State licensing and scope-of-practice laws. We believe the greater the flexibility that hospitals, medical staffs, and individual physicians have to enlist the services of non-physician practitioners to carry out the patient care duties for which they are trained and licensed, the better the quality of care will be for patients. Therefore, in this final rule, we are both modifying the proposed changes to the Medical staff requirements as well as revising portions of the current requirements of this section in the following manner:

- Removing the proposed concept of physicians and other practitioners being privileged to practice without appointment to the medical staff;
- Removing the proposed regulatory language that the granting of privileges is done in accordance with ''hospital policies and procedures;''
- Aligning the new regulatory language at § 482.22 (a) with that currently found in the Governing body CoP (§ 482.12(a)(1)) regarding the governing body requirement to determine, in accordance with State law, the categories of practitioners who are eligible for medical staff appointment;
- Revising existing § 482.22(a)(2) to require the medical staff to examine the credentials of all eligible candidates and make recommendations for medical staff membership to the governing body in accordance with State law, including scope of practice laws, and with medical staff bylaws, rules, and regulations; and
- Revising existing § 482.22(a)(2) to require that a candidate recommended by the medical staff and appointed by the governing body be subject to all medical staff bylaws, rules, and regulations in addition to the requirements in this section.

We believe that these changes would not only satisfy the recommendations of the IOM report, but would also directly address the issues raised by commenters who opposed our proposed revisions. The regulatory language that we are finalizing here emphasizes the collaborative nature that must exist between the medical staff and the governing body of a hospital. It is a system of checks and balances between the governing body and the medical staff (and, to a certain degree, also between an individual practitioner and the hospital's medical staff and governing body). Each has its own areas of authority. The medical staff has oversight of all practitioners practicing as part of the medical staff through processes such as peer review and re-privileging. The governing body has the authority to establish the categories of practitioners (regardless of the terms used to describe those categories) who are eligible for privileges and medical staff appointment, but must rely on the medical staff to apply the criteria for privileging and appointment to those eligible candidates and to make their recommendations before the governing body makes a final decision to appoint or not appoint a practitioner to the medical staff. With the changes contained in this final rule, we are ensuring that these areas of authority remain intact.

The changes also leave room for a hospital or a governing body, after considering the recommendations of its medical staff, to appoint non-physician practitioners to the medical staff and to grant them privileges that are in alignment with their professional education and training to the full extent allowed under State licensing and scope-of-practice laws. We encourage medical staff and hospitals to take advantage of the expertise and skills of these non-physician practitioners when making recommendations and appointments to the medical staff. We agree with commenters that an appointment to the medical staff engenders a sense of mutual responsibility for the activities and work of the medical staff for physicians; however, we believe that these sentiments are also engaged when non-physician practitioners are appointed members of a hospital's medical staff. We encourage physicians and hospitals to enlist qualified non-physician practitioners to fully assist them in taking on the work of overseeing and protecting the health and safety of patients. This applies not only to the ''work'' of the medical staff—such as quality innovation and improvement, best practices application, and establishment of professional standards—but also to the everyday duties of caring for patients. As many of the commenters expressed, we also believe that an interdisciplinary team

approach to patient care is the best model for patients. However, we also agree that physicians, owing to their training and expertise, must be the leaders in overall care delivery for hospital patients. The changes that we are making to the requirements clarify and affirm these precepts. However, this should not be construed to limit the authority of a physician to delegate tasks to other qualified healthcare personnel or to limit the authority of a non-physician practitioner to be responsible for the care of an individual patient, or patients, as allowed in accordance with State laws, medical staff bylaws, and hospital policies.

Comment: A significant number of comments were supportive of the proposed changes to the Medical staff CoP at § 482.22(b) that would expand the list of physicians who would be eligible to assume direct leadership responsibilities for the organization and accountability of the medical staff to include doctors of podiatric medicine (DPMs), when permitted by the State law of the State in which the hospital is located. This proposal would permit a DPM to fill this role, in addition to the categories of physicians that are allowed to assume this leadership position under the current requirements: an individual doctor of medicine or osteopathy or, when permitted by the State law of the State in which the hospital is located, a doctor of dental surgery or dental medicine. Many of these commenters cited the similarities in education, training, and experience that DPMs share with their allopathic and osteopathic colleagues as reasons for their support of this proposed change to the medical staff leadership requirements.

One commenter expressed support for the proposal to include DPMs as eligible leaders of the medical staff and recommended that CMS extend this provision to other non-physician practitioners. However, the commenter pointed out that the non-physician practitioners eligible to fill the medical staff leadership role in a hospital should be limited to APRNs. The commenter recommended that PAs should be excluded from eligibility for the medical staff leadership role in hospitals because they believe that PAs lack the level of education, training, and experience that APRNs possess.

There were also a significant number of commenters who opposed this proposed change. These commenters expressed concern over the precedent that this sets and maintained that practitioners who are not medical doctors or doctors of osteopathy should not be authorized to hold leadership positions on the medical staff of a hospital. The commenters also believe that in many hospitals, ''a 'Chief Medical Officer,' someone hired by the hospital who is not a physician, is appointed to serve in a leadership position that would otherwise be held by a member of the medical staff.'' They stated that they believe our proposal to include DPMs could result in more of this type of activity and asked that we carefully consider the intended results of our proposed change to this provision.

Response: We appreciate the comments that supported the proposed change. We also thank the commenters who expressed an opinion that was in opposition to our proposed revisions to this provision of the Medical Staff CoP.

However, we do not see a connection between our proposal to include DPMs as potential candidates for medical staff leadership in any hospital where they are members of the medical staff and the alleged practice to which the commenters referred. Nor do we believe that the commenters opposing this proposal have provided any evidence that would lead us to believe that DPMs are not qualified to lead the medical staff of a hospital and that to do so would place the health and safety of patients at risk. Section 1861(r) of the Act includes DPMs under the definition of physician and nothing in the statute precludes a DPM from leading a medical staff if the medical staff selects one for this position and the governing body approves of the medical staff's selection. As we stated in the preamble of the proposed rule, we believe that DPMs possess the education, training, and experience that makes them qualified to hold such a leadership position if the hospital and its medical staff chooses to exercise this option. In addition, while we recognize the education, training, and experience that non-physician practitioners bring to the care of hospital patients, we disagree with the commenter who recommended that APRNs be included in the list of eligible medical staff leaders, since this category of practitioner does not meet the statutory definition of physician. However, as we have noted above, we continue to encourage and support the inclusion of APRNs, PAs, and other non-physician practitioners on hospital medical staffs, as we believe they can assist physicians with the oversight and improvement of patient care. Therefore, we are finalizing this requirement as proposed.

4. Nursing Services (§ 482.23)

We proposed to revise the hospital nursing service requirements at § 482.23 (b)(4), ''Nursing services,'' which currently requires a hospital to ensure that the nursing staff develop, and keep current, a nursing care plan for each patient. We proposed that for those hospitals that use an interdisciplinary plan of care in providing patient care, the care plan for nursing services may be developed and kept current as part of the hospital's overall interdisciplinary care plan.

We proposed to revise the current Nursing services CoP at § 482.23(c) by adding new provisions that would allow for drugs and biologicals to be prepared and administered on the orders of practitioners other than those specified under § 482.12(c). We also proposed further revision to § 482.23(c) to add a new provision allowing orders for drugs and biologicals to be documented and signed by practitioners other than those specified under § 482.12(c). We proposed to allow for these two revisions only if such practitioners were acting in accordance with State law, including scope-of-practice laws, and only if the hospital had granted them privileges to do so.

Within this section of the Nursing services CoP, we also proposed changes that would allow hospitals to use standing orders. At § 482.23(c)(1)(ii), we proposed to allow for the preparation and administration of drugs and biologicals on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders, but only if such orders meet the requirements of § 482.24(c)(3), as discussed below.

We also proposed to eliminate the requirement, currently at § 482.23(c)(3), that non-physicians must have special training in administering blood transfusions and intravenous medications.

At § 482.23(c)(4) we proposed that those who administer blood transfusions and intravenous medications do so in accordance with State law and approved medical staff policies and procedures. We proposed to retain § 482.23(c)(4) and redesignate it at § 482.23(c)(5), without any content change.

We also proposed additional revisions at § 482.23(c)(6) that would allow hospitals the flexibility to develop and implement policies and procedures for a patient and his or her caregivers/support persons to self-administer specific medications (non-controlled drugs and biologicals). We proposed requirements that a hospital would have to meet if it chooses to implement such a policy.

Nursing Services 482.23(b)(4)—Use of an Interdisciplinary Plan of Care

Comment: A majority of commenters supported the revisions to this provision that would allow for the incorporation of the nursing care plan into the larger interdisciplinary care plan. A few commenters asked that we clarify what would be required regarding documentation of the interdisciplinary plan.

Several commenters recommended that CMS add a requirement that all hospitals implement a hospital-wide staffing plan that would establish an appropriate number of registered nurses on each unit to meet the needs of the patients and the expectations of those units. They stated that the plan should take into account factors present on each unit during each shift, such as: the number of patients and the level and variability of intensity of care; the level of education, training, and experience of RNs providing direct patient care; and non-patient care-related duties that nurses oversee.

Response: We appreciate the comments supporting the rule as well as the suggestions for additional staffing requirements. The required documentation for the interdisciplinary care plan should follow the current documentation policies that hospitals are using to document the services provided by other disciplines to patients, such as services provided by physical therapists, occupational therapists, speech-language pathologists, and others. Documentation should follow the standards of practice for those disciplines in addition to any specific requirements that a hospital might want to establish. The documentation must also comply with the requirements of the CoP at § 482.24, Medical records services.

Regarding the recommendations for additional staffing requirements, the regulation already requires the hospital to have adequate numbers of nurses to provide nursing care as needed, and makes it the responsibility of the director of nursing services to determine the types and number of nursing personnel and staff necessary to provide nursing care for all areas of the hospital. Therefore, we do not see the need to require any additional or more prescriptive regulations to address the nursing issues expressed by the commenters.

Comment: One commenter stated that the Nursing Care Plan should not be merged with the service notes and treatment plans of other professionals for reasons of patient safety, transparency, authority and accountability to professional practice standards. The commenter believes that entries made by an RN should not be replaced with entries made by other disciplines. Another commenter stated that the interdisciplinary care plan should be the responsibility of nurses, who are better trained and positioned to ensure that the plan is patient-centered and well-coordinated between disciplines. Another commenter recommended that we change 482.23(b)(4) to ensure that the nursing staff provides evidence in the medical record that the unique and changing needs of the patient are considered and met. They stated that this medical record documentation can be part of a nursing care plan, an interdisciplinary care plan, or a clinical pathway, or through other methods approved by the hospital.

Response: While we understand to a certain degree the concerns expressed regarding the care plan, we do not understand the one commenter's concern that nursing entries would be replaced by entries made by other disciplines. The provision does not require a hospital to replace its nursing care plan with an interdisciplinary care plan nor does it require (or even permit) nursing entries to be replaced by entries made by another discipline. We proposed that the nursing care plan be permitted to be part of an interdisciplinary care plan based on hospital policy. The hospital is responsible for ensuring that the nursing staff develops and keeps current a nursing care plan for each patient and the hospital can determine if the nursing care plan is a part of a larger, coordinated interdisciplinary care plan. As proposed, the requirement was an option intended to provide flexibility for hospitals that believed patient care plans should reflect coordination of care by the various disciplines providing services to patients.

Additionally, we disagree with changing the regulation by adding language that requires nurses to provide evidence in the medical records regarding how the needs of patients are met. In addition to the current requirement that an RN must supervise the nursing staff and evaluate the nursing care for each patient, the hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient even if it is part of a larger, coordinated interdisciplinary care plan. We believe that the current requirements adequately ensure that the unique needs of each patient are addressed.

Comment: A few commenters recommended that we require hospitals to conduct, no less than annually, an evaluation of the staffing plans based upon an assessment of patient outcome data that is nursing sensitive and that hospital staffing plans be made available to the public. The commenters also recommended that a perioperative RN should be present in each operating room acting as a circulator throughout the duration of each surgical procedure.

Response: We agree with the commenters that hospitals should evaluate their nurse staffing plans and ensure that the appropriate staff is available to provide quality health care to all patients. We believe that it is implicit in the requirement for the director of nursing to determine the types and numbers of nursing personnel necessary that the director of nursing would periodically re-evaluate staffing plans to ensure that the nursing care needs of patients are met.

Comment: One commenter recommended that the interdisciplinary team should include the patient/patient advocate/power of attorney in addition to the traditional healthcare team of providers to participate in the plan of care.

Response: The regulations at 42 CFR 482.13 establish the right of the patient, or the patient's representative, as applicable, to participate in the development and implementation of his or her plan of care and to be informed of the patient's healthcare status and to make informed decisions about his or her care. We believe it would be redundant to also include these rights in the regulatory text related to the nursing or interdisciplinary plan of care.

Nursing Services 482.23(c)(1)(i)—Drugs and Biologicals May Be Prepared and Administered on the Orders of Other Practitioners (in Accordance With State Law and Scope of Practice Laws)

Nursing Services 482.23(c)(1)(ii)—Drugs and Biologicals May Be Prepared and Administered on the Orders Contained Within Pre-Printed and Electronic Standing Orders, Order Sets, and Protocols for Patient Orders

Nursing Services 482.23(c)(3)(iii)—Orders for Drugs and Biological May Be Documented and Signed by Other Practitioners

Comment: A significant number of commenters supported the proposed changes that would allow drugs and biologicals to be prepared and administered on the orders of other practitioners not specified under § 482.12(c) if the practitioners are acting in accordance with State law, including scope-of-practice laws, and if the

hospital has granted them the privileges to write orders.

Commenters were also very supportive of the inclusion and allowance for standing orders in the proposed revisions to the Nursing services requirements. We also received comments specifically supporting the use of standing orders to encourage immunizations, notwithstanding the regulations at § 482.23(c)(3), which allow for nurse-initiated administration of influenza and pneumococcal polysaccharide vaccines per physician-approved hospital policy after an assessment of contraindications. Commenters were enthusiastic about the positive effect that they believed the use of standing orders would have for the broader patient population in general and for hospital infection control efforts specifically in terms of a possible increase in the immunization rate.

Similarly, there was extensive support for the proposed revisions to allow for ''other practitioners not specified under § 482.12(c)'' to document and sign orders for drugs and biologicals, provided that such practitioners meet the provisions discussed above. Many commenters stated that they believe the changes will allow other qualified practitioners the flexibility to address the immediate needs of patients without delay and that it will increase efficiency and the quality of patient care at the same time. One commenter stated that the changes will ''lessen the impact of the current shortage of general practitioner MDs, thereby allowing patients fuller access to care'' by allowing other qualified practitioners the ''ability to write orders and to practice to the full extent of their scope of practice and State law.''

Response: We thank the commenters for their support of the proposed revisions to these provisions in the Nursing services CoP. We agree that the changes will help to eliminate unnecessary delays in treatment, improve access to care for hospital patients, and improve immunization rates for the broader patient population. We appreciate the support from commenters on the proposed standing orders provisions contained in this section and will discuss the comments on these changes in the Medical record services section that follows this section. However, we should point out that the changes finalized here and in the Medical record services section regarding the use of orders (including pre-printed and electronic standing orders, orders sets, and protocols) do not allow for the use of nurse-initiated orders (beyond, or in addition to, those currently allowed for influenza and pneumococcal vaccination) without an authenticated physician or practitioner order. We should also note that while the provisions finalized here will allow for a qualified non-physician practitioner to write orders and to practice to the full extent of his or her State scope of practice, some insurers, including Medicare, may only pay for the services ordered by a physician or for the services ordered incident to a physician's services.

Comment: Several commenters took exception to the fact that the proposed language in these provisions does not defer to medical staff bylaws, rules, and regulations. Other commenters also expressed serious concerns about what they categorized as ''the proposal to expand the types of practitioners who are able to administer drugs and biologics, particularly as [such proposal] relates to anesthesia and pain management.'' The commenters believe that expanding the number of non-physician providers able to administer certain drugs, such as opioids, would only exacerbate the problem of prescription drug overdoses. They urge CMS to withdraw the proposal on the grounds that ''non-physician providers may not have sufficient education or training in the proper prescribing of opioids, including patient selection and risk assessment.''

Response: We thank the commenters for noting our failure to properly defer to medical staff bylaws, rules, and regulations with regard to this issue and we agree that, in addition to our deference to State laws and hospital policies, the provisions must also defer to the bylaws, rules, and regulations of the hospital's medical staff. Therefore, we are revising the proposed requirements to include this reference in this final rule.

Regarding the comments that expressed concern over non-physician providers ''administering'' certain medications related to anesthesia and pain management, such as opioids, we believe that the commenters may have been confused over the language of the proposed requirements. We point out that the requirements that we are finalizing in this rule are with regard to allowing drugs and biologicals to be prepared and administered on the orders of other practitioners not specified under § 482.12(c) only if such practitioners are acting in accordance with State law, including scope-of-practice laws, and medical staff bylaws, rules, and regulations. However, the commenters also mentioned the prescribing of opioids by practitioners other than physicians and believe that these practitioners may lack the education and training to adequately and safely prescribe (or order) these types of drugs for patients. We respectfully disagree and maintain that if these practitioners, in ordering drugs and biologicals, are acting in accordance with the State laws (including scope-of-practice laws) of the State in which the hospital is located, and if the hospital, through its policies, and the medical staff, through its bylaws, rules, and regulations, authorize them to do so, then they have been determined competent to order these medications.

Nursing Services 482.23(c)(3)—Administration of Blood Transfusion and Intravenous Medications (in Accordance With State Law and Approved Policies and Procedures) by Trained Non-Physician Practitioners

Comment: Many commenters agreed with the deletion of the requirement that non-physicians have special training in administering blood transfusions and IV medications. However, several commenters stated that, given the immediate and significant risk to a patient if these procedures are done incorrectly, the only personnel permitted to do them should be an RN, APRN, PA, or physician. They also argued that this personnel requirement should be added to the regulatory language. Another commenter stated that we should clarify in the final rule that this revision includes all categories of APRNs (CRNAs, CNMs, CNSs, and NPs) who are acting in accordance with State law and hospital policy.

Response: We appreciate all of the comments supporting the proposed change. However, we want to clarify that only the non-physician personnel who have received training in administering blood transfusions and intravenous medications, in accordance with State law and approved medical staff policies and procedures, will be allowed to provide these services. We disagree with the suggestion that we specify the exact practitioner-types who are qualified to provide these services because we believe that these defined criteria will prevent unqualified personnel from administering blood transfusions and IV medications.

Comment: A few commenters opposed our eliminating the requirement that non-physicians have special training in administering blood transfusions. One commenter stated that while nurses may receive training in administering intravenous medication in nursing school, the training is often not comprehensive. Generic training on IV drug administration may not give individuals the appropriate awareness

of difficulties with administering special medications intravenously. Since intravenous drugs typically pose greater risks than orally administered drugs and they are typically used in patients who are ill, this change could have an adverse effect on patient safety. One commenter recommended that CMS allow registered nurses to explain and receive informed consent for blood transfusions. They stated that most facilities already use RNs to discuss the risks and benefits of blood transfusion with a patient. They also recommended that RNs be allowed to document a patient's informed consent without requiring the services of a physician because the current practice is cumbersome and causes undue delay in treatment.

Response: We respectfully disagree with the commenters. We proposed that blood transfusions and intravenous medications be administered in accordance with State law and approved medical staff policies and procedures. The majority of commenters stated that this training is standard practice and does not need to be prescribed in these regulations. Regarding the recommendation that CMS allow registered nurses to explain and obtain informed consent for a blood transfusions, the current requirements do not preclude nurses from performing this task. Informed consent is discussed in three locations in the CMS hospital CoPs: § 482.13(b)(2) pertaining to patients' rights; § 482.24(c)(2)(v), pertaining to medical records services; and § 482.51(b)(2), pertaining to surgical services. The corresponding guidelines to these three provisions contain extensive discussions regarding what constitutes a properly executed informed consent form, as well as information on what additional information might also be contained in a well-designed informed consent form. Hospitals must establish their own policies regarding informed consent, including which procedures require informed consent and who may obtain the informed consent.

Nursing Services 482.23(c)(6)—Patient Self-Administration of Both Hospital-Issued Medications and the Patient's Own Medications Brought Into the Hospital

Comment: The majority of comments received were in support of this revision that would allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and his or her own medications brought into the hospital. However, many commenters advised that patient self-administration would only be successful if the hospital had a process in place to evaluate each patient to determine if self-administration was appropriate for that particular patient. One commenter stated that ''used properly and with the right patients, self-administration can be an extraordinarily helpful tool for teaching self-care as a patient and his or her family begin the transition back home,'' and further emphasized allowing for some flexibility in the implementation of this process so that nurses, physicians, and other practitioners would be fully able to exercise their clinical judgment when deciding which patients were appropriate for self-administration of medications. Many commenters believed that this type of medication regimen reinforcement prior to discharge could help to reduce and prevent costly patient readmissions secondary to medication errors and non-compliance.

A number of commenters expressed their belief that patient self-administration of medications would actively engage the patient in his or her plan of care and could serve to keep the patient more fully involved in the treatment process, which could in turn reduce the length of stay for the patient and subsequently prevent the patient's readmission.

Response: We thank the commenters for their support of these revisions. We agree with the commenters who stated that a hospital program for patient self-administration of medications could be extremely beneficial for the appropriate patients if the proper precautions were taken in designing and implementing such a program. With regard to the comments that pointed out that teaching patient adherence to the proper medication regimen prior to discharge could have a positive impact on reducing hospital patient lengths of stay and readmission, we also agree, and encourage hospitals considering adoption of a medication self-administration policy to look to the medical literature for examples of best practices and their use in successful patient self-medication programs.

Comment: Several commenters opposed the proposal allowing for patient self-administration of medications. Some of these commenters expressed serious concerns about the proposal and focused on those aspects of the revisions related to the nursing education of patients and the subsequent nursing oversight of patients self-administering medications as well as the nursing documentation of patient self-administration. The commenters were concerned that these aspects of the policy would place undue burden on a nurse's already limited time for patient care. Commenters questioned how nurses would document patient self-administration in the patient's medical record if they did not administer or witness the administration of the medication.

A few commenters stated that they opposed the proposed revisions because of their concerns about medication safety, including the proper storage and security of medications, especially controlled substances; the time needed for hospital pharmacists to identify and label medications brought from home; control over which medications (and the dosages) the patient is taking; maintenance of needed supply of medications brought from home and procedures in event of shortage; administration of medications not approved for use in hospital; and quality and integrity of medications brought from home, including issues with expired medications brought from home. One commenter stated that we should clarify that a patient should not be allowed to bring their own drugs, except in rare and unavoidable circumstances. Other commenters stated that the proposed requirements were naïve and that they were clearly not developed by clinical professionals. These commenters also believe that these requirements would endanger the safety of the most vulnerable hospital populations: the elderly and the chronically ill. They pointed out that medication errors and compliance with medication regimens are often the cause for hospital admissions and readmissions.

Response: We appreciate the concerns that commenters have expressed and we have made some revisions to certain areas of the proposed requirements that we believe will address some of these concerns. Specifically, we have revised § 482.23(c)(6)(i)(D), § 482.23(c)(6)(i)(E), § 482.23(c)(6)(ii)(D), and § 482.23(c)(6)(ii)(E) in this final rule by now requiring the hospital to have policies and procedures in place to address the security of the medication(s) for each patient and to document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record for both hospital-issued medications and those brought from home. We believe that these changes will clarify the questions that we received through the comments regarding the security of specific medications as well as the procedures for documenting the self-administration

of medications when a nurse does not witness it.

We believe that the security of a patient's self-administered medications is extremely important, but it is an issue that does not lend itself well to a one-size-fits-all requirement similar to the one we originally proposed that would require a hospital to have policies and procedures in place to ensure the security of the medication(s) of each patient. We are aware that there are Federal and State laws, including the current Pharmaceutical services CoP at § 482.25, that require a higher level of security for certain medications (for example, controlled substances). We expect hospitals to comply with these already-established requirements and laws and we do not expect hospitals to include these medications and other similar medications and drugs as part of a patient self-administration program. Indeed, a hospital may find that there are other medications that it believes should be excluded from patient self-administration due to concerns over its own capacity to address the security of these medications for patients. A hospital may choose to have a policy where it maintains a list of medications that it excludes from self-administration entirely; to have a policy that addresses the security of a particular medication on a patient-by-patient basis; or to establish a policy that is a combination of both these approaches to medication security.

Hospitals are also free to establish different levels of patient self-administration (e.g., with or without a nurse present to supervise the self-administration) that could be determined either by the practitioner issuing the order to permit self-administration of specific medications or by the nurse after he or she conducts the assessment of the patient (or caregiver/support person) to determine his or her capacity for self-administration of the specific medications ordered. We would expect a nurse to exercise his or her clinical judgment and to inform the practitioner responsible for the care of the patient about any reservations the nurse might have regarding an individual patient's (or caregiver's/support person's) capacity to safely self-administer medications. We would also expect that a nurse would document the assessment of a patient's capacity to self-administer medications, highlighting the affirmative or negative findings along with any discussions that the nurse might have with the practitioner responsible for the care of the patient regarding the patient's capacity to self-administer.

Regarding documentation of self-administered medications, we believe our original proposed requirement for documentation was too rigid and introduced the possibility that a nurse would have to document un-witnessed patient self-administration of a medication in the same manner he/she would if he/she had witnessed it or had administered the medication to a patient himself/herself. That is why we are finalizing our revisions to the proposed requirements in this rule that will allow for a nurse to document the administration of the medication as reported by the patient (or the patient's caregiver/support person where appropriate). We believe that this represents a more realistic approach to documentation that does not require a nurse to document an action by the patient that she did not witness. Instead, the nurse now will have the option in these cases of documenting the patient's attestation of the medication self-administration.

Regarding the commenters' other concerns (which were largely focused on self-administration of medications brought from home), we note that this requirement will be an optional method for the administration of medications and that hospitals will still have the flexibility to prohibit patient self-administration of medications in any form. A hospital must determine for itself, through its medical staff and its nursing and pharmacy leadership, and in consultation with legal counsel and risk management, whether it believes that it can establish a medication self-administration program that will be safe as well as beneficial for patients. Studies indicate that a well-designed and implemented medication self-administration program can be both safe and beneficial for patients. In addition to presenting their own 2006 study in the Journal of Clinical Nursing (Grantham G, McMillan V, Dunn SV, Gassner L–A, Woodcock P (2006) Patient self-medication—a change in hospital practice. J Clin Nurs Aug;15(8): 962–970) Grantham et al. reviewed the literature for previous studies of hospital patient self-administration programs. These studies generally found that effective self-administration programs are associated with high levels of patient satisfaction as well as with increases in patients' knowledge, self-esteem, and independence. The authors also noted in their review of the literature that there is ''some evidence to suggest that patients who self-administer medications in hospital have fewer medication errors and medication-related problems postdischarge.'' Regarding the results of their own study, Grantham et al concluded that their program ''achieved high levels of nursing and patient satisfaction, contributed to efficient patient discharge and was safe.''

Should a hospital choose to establish such a program, we would expect it to comply with all of the requirements finalized here as well as with other existing laws and regulations pertaining to medications and their administration to patients.

Additional Comments Received Beyond the Scope of This Rulemaking

Comment: A commenter suggested that CMS should extend Part B coverage to all vaccines recommended by the CDC's Advisory Committee on Immunization Practices.

Response: We appreciate this comment, however no such changes will be made to this provision. This comment is outside the scope of this section and outside of the proposed rule.

5. Medical Record Services (§ 482.24)

The current requirements, at § 482.24(c)(1)(i), specify that all orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner. Current regulations also include an exception to this requirement at § 482.24(c)(1)(ii), which allows for the 5 year period following January 26, 2007, all orders, including verbal orders, to be dated, timed, and authenticated by the ordering practitioner or another practitioner who is responsible for the care of the patient as specified under § 482.12(c) and who is authorized to write orders by hospital policy in accordance with State law. This requirement has now expired and is no longer in effect. Additionally, § 482.24(c)(1)(iii) establishes that all verbal orders must be authenticated based upon Federal and State law; in the absence of a State law designating a specific timeframe for the authentication of verbal orders, this provision then specifies that all verbal orders must be authenticated within 48 hours.

We proposed to consolidate three existing provisions into one new provision at § 482.24(c)(2). Specifically, we would remove existing paragraphs (c)(1)(i) through (c)(1)(iii) and add a new § 482.24(c)(2). Existing paragraph (c)(2) would be redesignated as (c)(3). This new provision would retain the requirement that all orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner, but would add the

exception currently contained at § 482.24(c)(1)(ii) by allowing for authentication by either the ordering practitioner or ''another practitioner who is responsible for the care of the patient as specified under § 482.12(c) and authorized to write orders by hospital policy in accordance with State law.'' We also proposed to remove the sunset provision and the 48-hour timeframe requirement for authentication of orders and instead defer to hospital policy and State law for establishment of any timeframe. We noted that if there was no State law establishing such a timeframe, then a hospital would be allowed to establish their own timeframe for authentication of orders, including verbal orders.

We proposed changes to the Medical records services CoP that would allow hospitals to use standing orders as long as certain provisions were met. We proposed new provisions to § 482.24(c)(3) that would allow a hospital to use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital: (1) Established that such orders and protocols had been reviewed and approved by the medical staff in consultation with the hospital's nursing and pharmacy leadership; (2) demonstrated that such orders and protocols are consistent with nationally recognized and evidence-based guidelines; (3) ensured that the periodic and regular review of such orders and protocols was conducted by the medical staff, in consultation with the hospital's nursing and pharmacy leadership, to determine the continuing usefulness and safety of the orders and protocols; and (4) ensured that such orders and protocols were dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or another practitioner responsible for the care of the patient as specified under § 482.12(c) and authorized to write orders by hospital policy in accordance with State law.

Comment: Concerning proposed § 482.24(c)(3)(i) and (iii), some commenters recommended removing the language, ''in consultation with the hospital's'' after ''staff'' so that the sections would read, ''medical staff, the hospital's nursing and pharmacy leadership.'' Nursing and pharmacy leadership would then be full partners in both approving pre-printed and electronic standing orders, order sets, and protocols for patient orders and ensuring there is a periodic and regular review of these orders. One commenter pointed out that these types of orders are often multi-disciplinary and comprehensive and patients would benefit from a more broad-based development and implementation of these orders and protocols.

Response: We agree that the nursing and pharmacy leadership of a hospital should be full partners in approving pre-printed and electronic standing orders, order sets, and protocols and in ensuring that these orders are periodically reviewed to determine the continuing usefulness and safety of the orders and protocols. Therefore, in this final rule, we have removed the language, ''in consultation with'' and added, ''and,'' after ''medical staff.'' Thus, the language in both §§ 482.24(c)(3)(i) and (iii) reads, ''medical staff, and the hospital's nursing and pharmacy leadership.''

Comment: We received some comments that requested further guidance or clarification concerning the proposed changes in this section. One commenter noted that the proposed requirements related to verbal orders and standing orders did not address residents. The commenter requested that CMS use IGs to thoroughly consider issues related to residents and ensure that the requirements do not become an impediment to the residents' education. The commenter also requested that the interpretative guidelines address certain specific issues.

Response: CMS will develop IG documents after the publication of this final rule to assist hospitals, surveyor, and the public in implementing this final rule. In developing that guidance, we will consider the commenters' recommendations.

Comment: We received one comment requesting that we remove the word, ''promptly,'' in § 482.24(c)(2) and replace it solely by reference to timeframes established by hospital policy.

Response: We do not agree with the commenter. With the removal of the 48-hour requirement for the authentication of orders from the hospital CoPs, the timeframe for authenticating orders would be determined by hospital policy in accordance with State law. However, we believe that quality patient care requires that authentication of orders should be done in a timely manner. Hence, we have left the word ''promptly'' in this provision.

Authentication of Orders by ''Other Practitioners''

Comment: We received numerous comments on our proposal at § 482.24(c)(2) that would allow other practitioners who were responsible for the care of a patient as specified in § 482.12(c) and authorized to write orders by hospital policy in accordance with State law to authenticate an ordering practitioner's orders, including verbal orders, beyond the sunset date of the current regulation. Some of the commenters noted that the requirement to have the ordering physician authenticate the order was overly burdensome to hospitals, doctors, and the nursing staff and did not result in any benefit for patient safety. They indicated that this change would give hospitals more flexibility so that they could focus on efficient, safe, high quality and patient-centered care. Some commenters noted that it was particularly important in certain cases, such as situations where there are residents who rotate between multiple institutions, restrictions on duty hours, and in situations where practitioners practice in rural areas.

Response: We thank the commenters for their support for the proposed changes to this section.

Comment: We received one comment that expressed concerns over the qualifications of the practitioners who would have authority to authenticate orders. A national organization of pediatricians stated that, in the case of pediatric patients, only a practitioner credentialed in pediatric care should authenticate orders.

Response: We understand the commenter's concerns. However, authentication of an ordering practitioner's orders must be ''by hospital policy and in accordance with State law.'' Hospitals may chose to restrict which practitioners it would authorize to authenticate another practitioner's orders. For example, as with the commenter's example, a hospital could choose to restrict authentication of orders for pediatric patients to practitioners who are privileged to provide pediatric care. We are confident that hospitals will address these issues in their policies.

Comment: We received several comments, including comments from advanced practice registered nurses (APRNs), national associations for both registered nurses and APRNs, and a medical center that suggested that limiting the practitioners who could authenticate an ordering practitioner's order to practitioners listed in § 482.12(c) would exclude APRNs and other non-physician practitioners. Some of these commenters noted that health care is increasingly provided by interdisciplinary teams and that the previous limitation created an undue burden. Some commenters stated that since APRNs and other practitioners were allowed to order drugs and biologicals if they had been granted hospital privileges to do so and they

were acting in accordance with State laws, including scope-of-practice laws, then those practitioners should be allowed to authenticate orders. The commenters recommended either deleting the reference to § 482.12(c), adding APRNs and other advanced practitioners to the list in § 482.12(c), or explicitly stating the APRNs could authenticate orders for other practitioners.

Response: We agree with the commenters that APRNs and other non-physician practitioners should have the authority to authenticate orders. Regarding the reference to § 482.12(c), we must note that this paragraph applies only to Medicare patients and is based on the statutory language at subsections 1861(e) and (r) of the Social Security Act. Even with regard to Medicare patients, the language at § 482.12(c) does not entirely exclude APRNs and other non-physician practitioners from authenticating orders. Section 482.12(c)(1)(i) states that, ''This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State's regulatory mechanism.'' If State law and a hospital's policy allow PAs and APRNs to authenticate orders, a physician could delegate that authority to them with regard to Medicare patients.

However, in analyzing these comments and in preparing our responses to them, we came to the conclusion that this reference to § 482.12(c) was inappropriately inserted into this section of the CoPs, most likely when revisions to this section were finalized in the November 27, 2006 rule (71 FR 68694). Since § 482.12(c) is still statutorily required with regard to practitioners and the responsibilities for the admission and care of Medicare patients, we have not made any changes to § 482.12(c) as the commenters recommended. However, we do believe that the removal of the reference to § 482.12(c) is warranted in that the requirements discussed here apply to all patients and not Medicare patients exclusively. Therefore, in this final rule, we are revising this provision to delete the reference to § 482.12(c) and to require that all orders must be authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations. We point out that we are taking the opportunity to also revise the language pertaining to State law, hospital policies, and medical staff bylaws, rules, and regulations in order to make it consistent with the changes we have made elsewhere in this rule that were based on comments received and which are consistent with industry practice.

Comment: We received a comment from a medical society that supported the easing of the timeframe for authentication of verbal orders; however, the commenters had concerns with the proposal to allow authentication of verbal orders by other practitioners. They were concerned about how orders could be interpreted and how this could affect patient care. They recommended that CMS not finalize the proposal to permit the authentication of orders by other practitioners.

Response: We disagree with the commenter. The commenter did not offer any evidence that having one practitioner authenticate the orders of another practitioner would have a negative impact on patient care. In fact, most of the commenters for this proposed change indicated that they thought it would not only reduce the burden to hospitals, practitioners, and nurses, but would also improve patient care.

Comment: We received one comment from a hospital association that stated the changes proposed to verbal order authentication provision could result in the unintended shift of liability to the hospital and hospital personnel receiving verbal orders and away from the physician/practitioner who bears ultimate responsibility for ensuring the medical necessity of the order. They stated that some States do not have specific timeframes for authentication. Some States defer to Federal regulations, and some State provisions contain ambiguous terms such as ''in a manner consistent with good medical practice'' or ''before billed.''

Response: Issues surrounding a hospital's tort liability concerning verbal orders authentication are State law matters and beyond the scope of this rule. Moreover, a hospital is free to adopt a more stringent policy than that required under the regulations, should it believe it is prudent to do so.

Comment: We received one comment in which the commenter supported expanding the eligibility of qualified practitioners to authenticate verbal orders. However, they asked for clarification regarding the CMS definition of ''another practitioner who is responsible for the patient.'' They noted that the definition of ''responsible'' could have practice implications for multiple providers and could increase costs by adding unnecessary physician supervision.

Response: CMS will develop IGs after the publication of this final rule to assist with the implementation of this final rule for providers, surveyors, and the public. We will consider the commenter's request in developing those guidelines. In addition, we believe that hospitals would address which practitioners would be deemed ''responsible for the patient'' in their policies.

Elimination of the 48-Hour Requirement for Authenticating Orders

Comment: We received several comments and most were supportive of the proposal to eliminate the requirement for an ordering practitioner to date, time, and authenticate orders within 48 hours.

Response: We would like to thank the commenters for their support of our proposal. We have finalized this section as proposed.

Comment: We received a few comments that expressed concern about possible errors. One commenter questioned who would catch any errors in orders if the ordering practitioner did not authenticate the order within 48 hours. Some commenters were concerned about whether the individual receiving the order would accurately interpret the order and the impact that could have on patient care. Another commenter stated the 48-hour requirement did nothing for patient safety and the issue really was whether the nursing staff immediately read back and verified the verbal order with the practitioner. One of these commenters recommended not finalizing the language that would permit other practitioners to authenticate orders.

Response: We agree with the commenters that the possibility of errors associated with verbal orders is an important issue, and that is why we continue to believe that hospitals should make efforts to minimize the use of verbal orders. We also agree with the commenter that it is expected that the standard practice would be for the person taking the order to read the order back to the practitioner to ensure that they have correctly understood it. In addition, this final rule does not mandate that a hospital allow other practitioners to authenticate an ordering practitioner's orders. Other practitioners can only authenticate orders if, among other requirements, it is in accordance with hospital policy and State law. Therefore, we disagree with the commenter that recommends not finalizing this provision. Thus, we have

not made any changes to the language in proposed § 482.24 to add any additional requirements for verbal orders.

Comment: A hospital association questioned why CMS and physicians continue to support time periods for other types of physician documentation (for example, history and physicals, anesthesia evaluations, review of restraint orders) but do not support the timeframes for verbal orders. The commenter gave the following reasons why CMS should reconsider the proposed policy of removing a defined timeframe for authentication: (1) Accountability of the prescribing physician/practitioner for medical necessity; (2) to validate that hospital staff received, transcribed and performed orders appropriately; and (3) to document that the physician/practitioner reviewed the patient's medical record entries, findings and other related documents when making medical decisions.

Response: We believe that the hospital CoPs should ensure that patients receive high quality care, while avoiding unreasonably burdensome requirements for hospitals. In the case of the requirement for an ordering practitioner to authenticate orders within 48 hours, the majority of commenters noted that the requirement was overly burdensome to hospitals, physicians, and nurses without providing any commensurate increase in patient safety/quality of care. In addition, we do not believe that having another practitioner authenticate an order for another practitioner would negatively affect a patient's care. The ordering practitioner, as well as the practitioner who authenticates the order, must be responsible for the patient's care. As other comments noted, interdisciplinary teams increasingly provide health care. All of the practitioners should be communicating and working together in their care of the patient. Therefore, we have finalized the removal of the requirement for authentication of orders by the ordering physician within 48 hours as proposed.

Standing Orders

Comment: We received numerous comments that were supportive of expanding the use of pre-printed and electronic standing orders, order sets, and protocols. Commenters noted that the use of standing orders contributes to patient safety and quality of care by providing evidence-based medicine and standardization. They indicated that using these types of orders would allow for faster implementation of care for patients. There would be less waste and procedural burden. Physicians would be able to spend more of their time on directly providing care to patients. Standing orders also allow other providers to take on additional tasks and simplify administrative processes.

Response: We thank the commenters for their support for the proposed change in this section. We have finalized this section as proposed.

Comment: We received a few comments that requested the development of further guidance on standing orders. A few commenters specifically wanted further guidance, especially for pediatric patients, vaccinations, and emergency department patients. One commenter noted that our proposed revisions did not address how the presence of resident physicians would affect the use of standing orders and requested that CMS address the use of standing orders as related to residents in the IGs. One commenter requested very specific issues be addressed in the IGs. A few commenters also requested that we provide definitions for ''pre-printed, standing orders, order sets, and protocols.'' They stated that we need to clarify the meaning of these terms if they are not used synonymously.

Response: Although we will develop further IGs after the publication of this final rule for hospitals, surveyors, and the public to implement this final rule, there is no basis in the regulations for our requiring hospitals to develop differential policies that specifically address pediatric or emergency department patients or particular types of drugs, with the exception of pneumonia and influenza vaccinations.

We are unclear what assertion the commenter is attempting to convey when the commenter refers to ''how the presence of resident physicians would affect the use of standing orders.'' Since the commenter did not explain this statement further, we can only assume that he or she meant to state that the presence of residents in a hospital would somehow affect whether a hospital might or might not use standing orders. With regard to resident programs and resident practice in hospitals, the IGs, in two separate instances, already discuss various aspects of resident practice in hospitals, though neither discussion addresses the use of standing orders by residents. Even though the IGs do not specifically address the use of standing orders by residents, we believe that it is useful to note where the current IGs do address other aspects of resident practice because these guidelines might be applicable to the comment as best we can discern it.

In the context of the requirements for patient restraint and seclusion orders (contained in the Patients' rights CoP at § 482.13(e)(5)), the use of standing orders by residents would be determined and authorized by a hospital's medical staff and residency program faculty as they see appropriate for the care of hospital patients and in accordance with any State laws governing the practice of residents in hospitals.

Regarding the commenters' requests for definitions of the various terms that we use in the provisions pertaining to standing orders, we refer the commenters to the proposed rule (76 FR 65895), which contains an extensive discussion of pre-printed and electronic standing orders, order sets, and protocols within both the Nursing services section and the Medical records services section of the preamble. Within the proposed rule, we also cite CMS S&C–09–10, which provides additional guidance on the use of standing orders. Over the last several years, our research into the issue of standing orders, including our discussions with hospital stakeholders, has led us to conclude that there is no standard definition for standing orders in the hospital community at large. Therefore, we chose to establish the criteria by which a hospital may establish standing orders, whether those orders are conveyed in printed or electronic form, in orders sets, or as protocols. Since agreement on what is meant by the term, ''standing orders'' does not exist, hospitals must focus on their compliance with the requirements finalized here, as they establish policies and procedures to create and use these types of orders.

Comment: We received a comment in which one commenter strongly disagreed with expanding the use of standing orders. The commenter believed that using standing orders would place the hospital staff in a position of having carried out orders from pre-printed orders, standing orders, order sets and protocols in good faith without an order from a physician, and that the absence of a physician order would potentially place the hospital and its staff in a legally compromising situation.

Response: The legal liability a hospital or hospital personnel could experience from using standing orders is beyond the scope of this final rule. However, hospitals and other healthcare institutions for many years have used standing orders. In addition, standing orders and protocols must meet all of the requirements at § 482.24(c)(3) of this final rule. Those requirements include authentication by either the ordering

practitioner or another practitioner responsible for the patient's care acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations (§ 482.24(c)(3)(iv)). First and foremost, there must be an initiating order (by a practitioner authorized to give such an order) for specific pre-printed or electronic standing orders, order sets, or protocols to be used for a particular patient. As we stated in the preamble to the proposed rule (76 FR 65896), hospital standing order policies and procedures ''should address well-defined clinical scenarios for the use of such orders'' and that CMS would expect that these same policies and procedures would also address the process by which a standing order is ''initiated by authorized staff.'' Within this same section of the proposed rule, we also stated, ''under no circumstances should a hospital use standing orders [pre-printed or electronic standing orders, order sets, and protocols] in a manner that requires any staff not authorized to write patient orders to make clinical decisions outside of their scope of practice in order to initiate such orders.'' In addition, the final rule allows hospitals the use of standing orders; it does not mandate their use. Therefore, hospitals concerned about potential legal liability associated with standing orders are not obligated to permit their use. It should also be noted that while standing orders may be used as prescribed under the provisions finalized here, hospitals should be aware that some insurers, including Medicare, might not pay for the services provided because of these orders.

Comment: We received a few comments that expressed concern about how the proposed language, ''authenticated promptly in the patient's medical record,'' could be interpreted. The commenters stated that they believed our intent was to ensure that the standing order or protocol appears in the patient's record. However, they stated that this language could be interpreted as requiring that each individual patient must have his or her own standing order for drugs and/or biologicals. They suggested that this interpretation would actually increase the burden on nurses.

Response: We appreciate the commenters concern about how some individuals could interpret the language in § 482.24(c)(3)(iv). The medical record is expected to include the standing order that was used for the patient, in order to fully and accurately document the care provided. In the case of an electronic health record or a pre-printed order set, it should not prove unduly burdensome to incorporate the standing order into the patient's record. Requiring a separate, subsequent authentication, which simply makes reference to the included order as the subject of authentication, also should not prove burdensome for practitioners. Both the current requirements and standards of practice regarding medical records dictate that any patient order given by a practitioner authorized to do so automatically becomes a required part of the patient's medical record and must be documented to reflect this, regardless of whether it is contained in pre-printed or electronic standing orders, order sets, or protocols, or whether it is a written or verbal order.

6. Infection Control (§ 482.42)

We proposed to eliminate the current provision at § 482.42(a)(2), which requires the infection control officer or officers to maintain a log of incidents related to infections and communicable diseases. We proposed to replace this provision with the requirement that the infection control officer or officers develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

Comment: Nearly all comments received stated that the present requirement for a separate infection control log is redundant and unnecessary, given advances in technology and surveillance systems. Many commenters also suggested that complying with the requirement for a separate infection control log merely diverts scarce resources from other efforts. Several comments noted that the proposed changes were both appropriate and timely. Several also expressed appreciation to CMS for the proposed change.

Response: We thank commenters for their support of our proposal. We agree with the commenters and will finalize our proposed change to remove the log. We recognize that infection control surveillance systems have made substantial advances since the time when this CoP was first implemented. We agree with commenters that technological advances have made the need for a separate infection log obsolete. CMS believes the revised rule presents hospitals with an important opportunity to reduce operating costs and promote patient safety goals.

Comment: One commenter specifically remarked that modern surveillance methodologies are targeted, in real time, and based on the epidemiology of the area being monitored. The commenter stressed that eliminating the requirement for a separate log will allow Infection Preventionists (IPs) and Hospital Epidemiologists (HEs) to better focus their efforts on useful data that will drive timely decisions to keep patients and staff safe. Similarly, several commenters suggested that the change would lead to better and more efficient collection of relevant data that can be used to enhance staff and patient safety in more rapid fashion.

Response: We recognize that modern surveillance systems include advanced infection detection, data collection and analysis, monitoring, and evaluation of preventive interventions. These modern systems and practices are consistent with the requirements retained at § 482.42(a).

We are aware that many hospitals use automated surveillance technology (AST) or ''data mining'' for identification and control of hospital-acquired infections (HAI) and implementation of evidence-based infection control practices. We believe that the algorithmic analysis of electronic health data offers much promise, and we are encouraged by the emerging data. (Halpin H, Shortell SM, Milstein A, Vanneman M (2011). Hospital adoption of automated surveillance technology and the implementation of infection prevention and control programs. *Am J Infect Control*, May;39(4):270–6.) and (Klompas M, Yokoe DS (2009). Automated surveillance of health care-associated infections. *Clin Infect Dis.* May 1;48(9):1268–75.).

We believe that eliminating the burden of having to maintain a separate log will provide hospitals with flexibility and free up time and resources that could otherwise contribute to patient safety efforts.

Comment: One commenter supportive of the proposed change noted it would not alter the current workflow.

Response: We thank the commenter for this feedback. This confirms our understanding that eliminating the requirement for a separate infection control log will not negatively disrupt hospital practices.

Comment: One commenter stressed the importance of recognizing the contributions and abilities of hospitals' infection control officers, noting that the vast majority of the officers are registered nurses who take their roles very seriously and have a very high level of professionalism and vigilance.

Response: We recognize the important contributions to infection control made by registered nurses and all health professionals. Indeed, success depends on each and every person involved in patient care, as so well portrayed in the

training video ''Partnering to Heal'' (HHS. ''Partnering to Heal.'' Accessed 12 January 2012 <*http://www.hhs.gov/ash/initiatives/hai/training/*>).

Comment: Some commenters expressed support for requirements allowing a hospital's infection control officer(s) to develop a system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel. A few commenters remarked upon the importance of a hospital's being able to design its own systems, tailoring them to its unique physical environment, resources, services and patient population.

Response: We agree. Apart from proposing to remove the requirement for a log at § 482.42(a)(2) and to adjust the formatting and numbering of the ''Organization and policies'' standard, we are leaving the remainder of this standard unchanged. We continue to believe that infection prevention and control efforts must be hospital-wide initiatives that take into account each institution's unique circumstances.

Comment: One commenter inquired into the evidentiary basis for or our proposal to eliminate the requirement for a log.

Response: We follow the medical literature on infection prevention and control closely, including research on surveillance. As noted above, we are aware of emerging technologies, such as automated surveillance technology (AST), and of the progress that is being made in surveillance and infection prevention and control practices, generally.

Both our understanding of this larger body of research and our own observations contributed to our conclusion that advances in infection control surveillance systems have made the need for a separate infection control log obsolete and to our proposal to eliminate the requirement for a separate infection control log. We also gave consideration to complaints from stakeholders that the log requirement is too prescriptive and burdensome.

In deciding to finalize our proposal to eliminate the log requirement, we would also note the universal support for this proposal from several major infection control groups, such as the Infectious Diseases Society of America (IDSA), the Association for Professionals in Infection Control and Epidemiology (APIC), and the Society for Healthcare Epidemiology of America (SHEA).

Comment: One commenter appeared to view our proposal to remove the requirement for a separate infection control log as a larger change to retool CMS reporting standards overall. The commenter speculated that our proposed changes would lead to the manipulation of data, make side by side comparisons nearly impossible and reduce transparency in recording and reporting.

Response: We do not agree that the removal of an outdated requirement for a separate infection control log would necessitate any additional changes to a hospital's infection control program. Our proposal to remove the separate log requirement is a single, targeted change to the infection control standard at 42 CFR 482.42(a).

We note that we have retained all other requirements at § 482.42, including the requirements at § 482.42(a) which require an infection control officer or officers to develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

To clarify further, our proposed rule introduced changes to Part 482 regarding CoPs for Hospitals. In a separate effort, CMS continues to employ hospital quality measures and continues its ''Hospital Compare'' initiative. See *http://hospitalcompare.hhs.gov/*. Neither the proposed rule nor this final rule touches upon this or any other effort by CMS.

Comment: One commenter stated that our requirements should be expanded and improved rather than be eliminated.

Response: We wish to clarify that we are not lowering our standards. As explained above, we believe that eliminating the requirement for a separate infection control log merely removes a redundancy that, in the modern context, adds cost but no value. We are mindful that healthcare-associated infections continue to be a major concern and are among the leading causes of death in the United States, accounting for an estimated 1.7 million infections and 99,000 associated deaths in 2002 (Klevens RM, Edwards J, Richards C, Horan T, Gaynes R, Pollock D, Cardo D. Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002. *Public Health Reports* 2007; 122:160–166.).

We would like to bring your attention to our efforts through the Partnership for Patients program, which was launched in the spring of 2011 with the twin goals of keeping patients from getting injured or sicker and helping patients heal without complication. (HHS. ''Partnership for Patients'' <*http://www.healthcare.gov/compare/partnership-for-patients/index.html*>).

We agree with the commenter that there might be room for improvement in the regulatory context. We may consider in future rulemaking further changes that would include an increased emphasis on infection control and prevention; further integration of infection control programs with the hospital's QAPI program; better alignment of a hospital's infection control efforts with nationally recognized guidelines; and a heightened role and accountability for a hospital's governing body in infection control program implementation and oversight.

Comment: One commenter suggested that CMS should also require protocols and staffing for antimicrobial stewardship as an integral component of infection control programs.

The commenter stated that the issue of antibiotic resistance has reached a critical point, as bacteria are becoming increasingly resistant to available antibiotics, and new drugs are not being developed at a pace necessary to address growing unmet medical needs.

The commenter also shared its forecast that the costs of including antimicrobial stewardship within the CoP related to infection control should be more than offset by savings generated. The commenter supported its statement by reference to a CDC summary of health economic research focused on employing antimicrobial stewardship programs with results showing significant cost savings. (CDC Impact of Antibiotic Stewardship Program Interventions on Costs. Retrieved Nov. 3, 2011 from *http://www.cdc.gov/getsmart/healthcare/support-efforts/asp-int-costs.html*).

Finally, the commenter suggested that, in a time where critical drug shortages have become increasingly more common, an effective antimicrobial stewardship program would promote efficient administration of appropriate therapies. In the FDA report on Drug Shortages released in October of this year, (FDA. ''A Review of FDA's Approach to Medical Product Shortages'' Accessed 12 January 2012 <*www.fda.gov/DrugShortageReport*>), antibiotics were the second largest therapeutic drug class to experience shortages, second only to oncology agents. The commenter suggested that by eliminating the inappropriate use and reducing the over-prescribing of antimicrobial agents, stewardship programs will preserve critical therapies that are in short supply.

Response: We thank the commenter for these suggestions. We agree that antimicrobial stewardship efforts are an important development in the context of infection control. We have not included any antimicrobial stewardship requirements in the present final rule. Such requirements were not proposed

and thus cannot be included at this juncture. However, we will consider these suggestions in future rulemaking.

7. Outpatient Services (§ 482.54)

Under the CoPs, the provision of outpatient services is an optional hospital service. However, if a hospital provides outpatient services, the services must meet the needs of patients according to acceptable standards of practice as required at § 482.54. The current provision at § 482.54(b)(1) also requires the hospital to assign an individual to be responsible for outpatient services.

We proposed revisions to this CoP that would allow hospitals greater flexibility in determining the management structure of outpatient services that would be tailored to the scope and complexity of the services offered by an individual hospital.

We proposed to change the existing provision at § 482.54(b) by revising the provision at § 482.54(b)(1) to allow hospitals to assign one or more individuals to be responsible for outpatient services. We also proposed to revise the current provision at § 482.54(b)(2), which currently requires a hospital to have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, by proposing to add a measure of flexibility such that hospitals would make their personnel decisions based on the scope and complexity of outpatient services offered.

Comment: We received numerous comments offering support for our proposal to remove the requirement for hospitals to have a single director of outpatient services. Many commenters noted that the change would be appropriate, given the complexities of modern hospital ambulatory care systems, in which technologies are changing and hospitals are increasing their outpatient service offerings. Many commenters stressed that the proposed change would free up limited resources, and characterized the current requirement as a costly and unnecessary administrative burden.

Some commenters also remarked that the change would help hospitals better ensure that individuals with the best expertise will direct each particular kind of care provided. Some also commented that the change would improve integration of their outpatient services with inpatient care while providing greater clarity to the management structure.

Response: We agree with the commenters that these changes will align the hospital CoPs with the current needs and practices of hospitals, and we are finalizing this change as proposed. We believe that removing the requirement for a single director of outpatient services will allow hospitals to better utilize their resources, particularly their staffing resources, and align them with the array of services they wish to offer.

Comment: Many commenters also expressly offered their support for the proposed regulatory language for hospitals to have ''appropriate professional and non-professional employees at each location where outpatient services are offered'' and to base this on ''the scope and complexity'' of the services.

Response: We are pleased to have received favorable feedback regarding this language. We will finalize this provision as proposed.

Comment: We received a comment seeking clarification about a statement in the proposed rule that ''hospitals have determined that it is in the best interests of patient safety and management practices to appoint more than one individual to oversee the various services offered and also to fully integrate their outpatient services with inpatient services.'' This commenter sought clarification as to whether the statement encompassed outpatient services provided by critical access hospitals and other community partners. The commenter expressed strong support for continuity of care and for having agreements in place to manage outpatient services and ensure good communication with a patient's medical home.

Response: We wish to clarify that the change to remove the requirement for hospitals to have a single director of outpatient services applies only to hospitals; it does not apply to critical access hospitals (CAHs), which do not have a comparable requirement for a single outpatient services director under the CAH conditions of participation. We agree that strong coordination with a patient's medical home would facilitate the provision of high quality, patient-centered care.

Comment: One commenter requested clarification between the CMS regulations at § 482.54 regarding Outpatient services and the regulations at § 482.12(c) regarding the care of patients. This commenter noted that if MD/DOs are required to see every patient, regardless of the medical reason for the appointment, then patients would be forced to wait for an available appointment when instead they could be seen and effectively treated within the scope-of-practice laws by a non-physician practitioner who is under a supervisory agreement with an MD/DO. The commenter also requested examples of ways in which a hospital would demonstrate evidence of a physician's involvement.

Response: We wish to clarify that the CMS requirements at § 482.12(c)(1) pertain only to Medicare patients. It should be noted that even with regard to Medicare patients, the requirement does not prohibit a patient from being treated by a non-physician practitioner who is a member of the medical staff and who is acting in accordance with his or her State scope of practice as allowed by medical staff bylaws, rules, and regulations and by hospital policy. Section 482.12(c)(1)(i) also contains language that states, ''This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State's regulatory mechanism.''

With regard to the commenter's request for examples of ways in which evidence of a physician's involvement would be demonstrated, the evidence of a physician's involvement in the care of a Medicare patient must be found in the patient's medical record. Examples of medical record documentation that support a specific physician's involvement in the care of a Medicare patient include, but are not limited to: the physician's name listed as the attending physician or physician of record; orders, progress notes, or H&Ps/updates authenticated by the physician; and any other documentation that could reasonably support a specific physician's involvement in the care of the patient.

8. Transplant Center Process Requirements—Organ Recovery and Receipt (§ 482.92)

The transplant center rule at § 482.92(a) and the Organ Procurement Organizations (OPO) rule at § 486.344(d)(2)(ii) and § 486.344(e) set forth requirements regarding blood type and other data verification, as well as documentation procedures.

We proposed to amend the existing regulations governing transplant centers by removing the provision at § 482.92(a) which requires the transplant team to verify blood type before organ recovery. We proposed to redesignate paragraphs (b) and (c) as (a) and (b), respectively. This would eliminate the requirement for a separate blood type and other vital data verification by a recovery team sent by a transplant center to recover an organ(s), if the intended recipient is known before organ recovery.

Comment: All of the comments were supportive of this requirement's removal. The commenters indicated that this requirement was redundant with the requirements in the OPO Conditions for Coverage (CfCs), unnecessary, and would not impact patient safety. They also indicated that the requirement was difficult to monitor and that the intended recipient could change before the organ was actually transplanted.

Response: We agree with the commenters that § 482.92(a) is redundant with the OPO CfCs. Section 486.344(d)(2)(ii) requires OPOs to compare the blood type of the donor with the blood type of the intended recipient prior to organ recovery, if the identity of the intended recipient is known. We will delete the current § 482.92(a) and redesignate the remaining subsections as (a) and (b). Thus, we have finalized the section as proposed.

Comment: One commenter did state that while they supported the removal of this requirement, multiple checks of blood type were required in light of recent medical errors concerning organ transplantation.

Response: We also agree with the commenter that multiple blood type checks are necessary to avoid errors in the transplantation of organs. In addition to the requirement for OPOs to check the blood type of the donor and the intended recipient as described above, transplant surgeons and another licensed health care professional must verify that the donor's blood type and other vital data are compatible with the intended recipient after the organ arrives at the transplant center (current § 482.92(b) and new § 482.92(a)). Thus, after removal of § 482.92(a), there are two mandatory checks to ensure that the blood type and other vital date of the donor and the intended recipient are compatible. This must be done for both deceased and living donors (§ 482.92(a) and (b)—as redesignated in the final rule).

Additional Comments Received Beyond the Scope of This Rulemaking

Comment: We received one comment suggesting that CMS clarify the outcome measures in the hospital CoPs for transplant centers. That commenter indicated that while the final rule for those requirements incorporated risk adjustment with regard to outcome requirements used to approve and re-approve transplant centers, they stated that the nature of the risk adjustment may not be fully appreciated. They believed that concerns related to the regulatory burden of these outcome requirements, while perhaps unwarranted, might be contributing to an unintended consequence of a sound public policy, namely a seemingly high organ discard rate.

Response: We appreciate the comment and the comment's concern. However, this comment is outside the scope of the proposed rule. Therefore, we not made any changes to the provision based on this comment.

9. Definitions (§ 485.602) and Provision of Services (§ 485.635)

The current CoP at § 485.602 and § 485.635(b) require CAHs to furnish certain types of services directly rather than through contracts or under arrangements. Specifically, the CoP at § 485.635(b) requires CAH staff to provide, as direct services, (1) diagnostic and therapeutic services that are commonly furnished in a physician's office or at another entry point into the health care system; (2) laboratory services; (3) radiology services; and (4) emergency procedures.

We proposed to eliminate the requirement at § 485.635(b) that CAH staff must provide certain services directly and proposed to change the heading of the standard, ''Direct services,'' to ''Patient services.'' We also proposed to revise the language in paragraphs § 485.635(b)(1) through (b)(4), ''that the CAH staff furnishes as direct services.'' We also proposed to eliminate the definition of ''Direct Services'' at § 485.602 since it will no longer be applicable.

We noted that the governing body, or the person principally responsible for the operation of the CAH under § 485.627(b)(2), would continue to be responsible for all services furnished by the CAH whether or not they are furnished directly, under arrangements, or under agreements.

Comment: The majority of commenters supported the proposed change, stating that it will allow CAHs more flexibility in meeting the needs of their communities with limited resources. This change will better enable CAHs to address staffing challenges, provide high-quality care to their patients, and provide CAH patients better access to care. A few commenters stated that allowing CAHs the flexibility in providing these services for their community while still maintaining responsibility and oversight for the services can generate cost savings that could be reallocated to other areas, such as quality improvement and patient safety.

One commenter expressed concerns that having non-employed providers may delay care and would urge caution in this area.

Response: We appreciate the comments supporting the rule and the comment that expressed concern regarding any potential delay in care. As stated by the majority of commenters, we believe that this change will enable CAHs to address staffing issues and to provide better access to quality health care. However, with this revision to provide CAHs with the flexibility to contract or arrange for patient services, we expect CAHs to ensure that they provide services that would facilitate timely diagnosis and treatment of their patients, as envisioned by the statute. We expect that delivering timely services will be best achieved by providing CAH services on-site at the CAH as much as possible, whether through CAH employees or through a contract or arrangement. At a minimum, we expect the services listed under § 485.635(b) to be offered by the CAH on-site.

Comment: Several commenters stated that this change will provide for greater partnerships with other local providers. One commenter stated that if CAHs are allowed to contract for services provided, CMS should state that a high preference is for CAHs to contract with other federally funded and designated programs like Federally Qualified health Centers (FQHCs), FQHC Look-Alikes, Rural Health Clinics (RHCs), and the health departments. One commenter stated that a CAH that sought to expand outpatient services should have to validate that there was a community need for the services it planned to deliver and submit a letter of support from all essential community providers validating that collaborative partnership with essential community providers had been developed and would be maintained. The commenter also stated that any CAH that sought to expand outpatient services should submit data annually to CMS regarding the cost, utilization, and outcomes of patient services delivered and that CMS should make this data available to the general public on an annual basis.

Response: We do not have the authority under Federal law to require CAHs to enter into contracts or arrangements for patient care services rather than provide them directly, or to require them to give preference in their contractual arrangements with certain types of Medicare-participating suppliers, such as FQHCs or RHCs. We also see no valid reason related to quality of care or patient safety for CAHs to have to bear the burden of justifying the need for additional outpatient services before the CAH may offer them. With respect to CAHs collecting and submitting data to us for

us to make public on their outpatient services, we already have in progress the development of measures of outpatient quality of care for publication on our Hospital Compare Web site, and are examining ways to include CAHs in future reporting. We agree with the commenters that removal of the requirement for certain services to be direct services will provide for greater partnerships with other local providers and suppliers, and we believe that CAHs will appropriately utilize the services of all providers and suppliers in their communities.

Comment: One commenter suggested that we eliminate the reference to ''direct services'' from the CAH standard at § 485.623(a), which states that the CAH is constructed to ensure access and to provide adequate space for the provision of direct services.

Response: Since we have proposed to eliminate the requirement that CAHs must provide services directly with CAH staff, and we have removed the definition for direct services at § 485.602, we agree with the commenter that we should remove the reference to ''direct services'' at § 485.623(a). We will also make a similar change to remove the reference to direct services at § 485.635(a)(3)(i), which requires the CAH's policies to describe all services the CAH furnishes directly and through agreement or arrangement.

Additional Comments Received Beyond the Scope of This Rulemaking

Comment: While we did not propose a change to this provision, some commenters requested reconsideration and revision of the requirement that CAH patient care policies and procedures be reviewed annually. They stated that policy review is extremely time consuming and requested that a biennial review, or longer which would be preferable.

Response: We appreciate the comments. However, this comment is outside the scope of the proposed rule and no changes will be made to this provision. We may consider these comments when undertaking future rulemaking.

B. Clarifying Changes

10. Pharmaceutical Services (§ 482.25) and Infection Control (§ 482.42)

In both § 482.25(b)(6) and § 482.42(b)(1) we proposed to replace the term ''quality assurance program'' with the more current term ''quality assessment and performance improvement program'' to clarify that we expect drug errors, adverse reactions, and incompatibilities to be addressed in a hospital's QAPI program, as required at § 482.21.

Comment: We received a few comments agreeing with the technical changes to replace the quality assurance term with the more current term ''quality assessment and performance improvement program.''

Response: We appreciate the support for these technical changes and will finalize the rule as proposed.

Additional Comments Received Beyond the Scope of CMS–3244

Comment: Several commenters recommended that we change the requirement to state that the professional responsible for the patient or who ordered the medications should also receive the report regarding pharmaceutical drug error, adverse event, or incompatibility issues. They stated that this would facilitate timely reporting to a Certified Nurse Midwife caring for a patient during labor and delivery, or to a nurse practitioner or physician assistant caring for a patient in the emergency room. Another commenter stated that the pharmacy department should be included in the development of criteria for pharmacist privileging decisions. One commenter questioned the timeframe for immediately reporting to the attending physician.

Response: We appreciate the comments. However, these comments are outside the scope of the proposed rule and no changes will be made to this provision. We may consider these comments when undertaking future rulemaking.

Comment: One commenter stated that we need to clarify changes to the quality assessment and performance improvement CoP.

Response: We did not propose to make any changes to the quality assessment and performance improvement CoP at § 482.21. We only proposed to make conforming changes to the pharmaceutical services CoP by replacing the term ''quality assurance program'' with the current term ''quality assessment and performance improvement (QAPI) program'' that is under the QAPI program CoP.

11. Personnel Qualifications (§ 485.604)

Many of the former EACH/RPCH CoPs were adopted for the new CAH program (see 62 FR 46008, August 29, 1997), including the definition for clinical nurse specialist. In this rulemaking, we proposed to revise the definition of a *clinical nurse specialist* (CNS) at § 485.604(a) to reflect the definition in the statute at § 1861(aa)(5)(B). Specifically, we proposed to change the definition at § 485.604(a) to state that a clinical nurse specialist is a registered nurse licensed to practice nursing in the State in which the clinical nurse specialist services are performed, that holds an advanced degree in a defined clinical area of nursing from an accredited educational institution.

Comment: A majority of commenters supported the proposed change. However, most of these commenters recommended that we include in the definition that the CNS be a registered nurse with a nursing degree at the master's or doctoral level from an accredited educational institution and authorized to practice based on State nurse licensing laws and regulations. They stated that this change will allow a CNS to practice in either the State in which they live or the State in which they provide services. Commenters also noted that not all advanced clinical degree nursing programs include the phrase ''CNS'' in their degree titles. Boards of Nursing in 38 States have determined the educational and practice requirements for individual programs prior to granting the title to work as a clinical nurse specialist in their States. The commenters stated that adding the language regarding State nurse licensing laws and regulations allows the State Boards of Nursing to determine whether the nurses' educational program is congruent with a CNS education. A few commenters stated that it is critical that language in the final regulation provide recognition of all existing CNSs, and in particular, those who practice in the area of mental health. One commenter recommended that we require CNSs to be certified by a national organization. However, the commenter also stated that they recognize the need to allow flexibility for States that do not yet require certification as a requirement for CNS practice and, at this time, it would be unfair to require that all CNSs be certified.

Response: We appreciate all of the comments supporting the proposed definition change as well as the suggestions for improving it. We will change the definition at § 485.604(a) to state that the term ''clinical nurse specialist'' is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed in accordance with State nurse licensing laws and regulations; and holds a master's or doctoral level degree in a defined clinical area of nursing from an accredited educational institution. Adding the phrase ''in accordance with State nurse licensing laws and regulations'' will ensure that an existing CNS will continue to be evaluated based

on their State licensing laws and regulations. We agree with the commenter that it would be unfair to require national certification for CNSs and we will not require such certification. We believe that requiring CNSs to have a graduate level education and to be authorized to practice based on State nurse licensing laws and regulations reflect the statutory definition of a CNS.

12. Surgical Services (§ 485.639)

The current surgical services CoP at § 485.639 was promulgated in 1995 (60 FR 45814, September, 1, 1995) to ensure adequate health and safety protection for patients. The provision of surgical services is not a required CAH service under the Act at section 1820(c); therefore, we proposed to change the introductory text before this CoP to clarify that surgical services are optional services for CAHs. We proposed to add the conditional clause, ''If a CAH provides surgical services,'' at the beginning of the introductory text. Also, to reflect the organizational structure CoP at § 485.627, we proposed to include the phrase, ''or responsible individual.'' The proposed technical change to the CoP introductory text is as follows:

''*If a CAH provides surgical services,* surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH or *responsible individual* in accordance with the designation requirements under paragraph (a) of this section.''

Comment: The majority of commenters supported the change clarifying the language regarding surgical services as an optional service. One commenter asked whether this rule change could lead to certain CAHs eliminating surgical services without giving thought to an alternative source for such services.

Response: We would like to clarify that this is not a substantive change in the regulation. CAHs are currently not required to provide surgical services. We proposed to revise the introductory statement to the CoP to clarify that CAHs are not required to provide surgical services. However, if a CAH provides surgical services, the CAH must comply with the surgical services CoP at § 485.639. Current CAHs should already be aware that this is an optional service and we do not believe that providing this clarifying language will result in a CAH eliminating their surgical services. In fact, we believe that clarifying the regulations that surgical services are optional will assist small rural hospitals that may be considering whether to seek CAH status. Therefore, we will finalize our proposed technical change.

Additional Comments Received Beyond the Scope of This Rulemaking

Comment: A few commenters stated that CMS should consider modification to the provisions at § 485.639, Anesthesia services, and require supervision of CRNAs to be consistent with State licensure requirements and elimination of the opt-out provision at § 485.639(e). Another commenter stated that CMS should reevaluate the physician supervision for CRNAs in CAHs and hospitals. There should be ongoing research regarding the need for the existing supervision requirements in the CoPs.

Response: We appreciate the comments. However, this comment is outside the scope of the proposed rule and no changes will be made to this provision.

C. Other Options Considered

In the proposed rule (76 FR 65891), we discussed alternative options for revisions that we considered, but did not propose. We also solicited comments and suggestions on additional reforms that would reduce burden on hospitals. Below are our responses to public comments on those alternatives, as well as a summary of additional recommendations submitted by commenters. See the October 24, 2011 proposed rule (76 FR 65891) for a detailed discussion of the other options we considered.

Medical Staff (§ 482.22)

In the proposed rule (76 FR 65899) we stated that we had considered changes to the Medical staff CoP at § 482.22 that would allow a multi-hospital system the option of having a single organized medical staff responsible for the quality of medical care provided to patients by all the hospitals in the system. We also considered, based on stakeholder feedback, revising the overall organizational structure of the CoPs to condense current requirements for departmental leadership responsibilities into a single, non-specific CoP that would allow hospitals to appoint hospital leaders based on hospital-established qualifications and needs specific to each hospital. We received many comments on these considerations, and responses to comments received for this section can be found below.

Comment: A number of commenters responded to our solicitation of comments on whether we needed to revise the Medical staff CoP at § 482.22 to further clarify that each hospital must have its own medical staff within a multi-hospital system, and there may not be a single medical staff for all of the hospitals within the system.

However, many of the comments reflected some confusion over our discussion of this issue. Some commenters interpreted our discussion as a proposal to allow a single medical staff for a multi-hospital system. In the proposed rule, we stated, ''We do not believe that the current CoP language implies that we require a single and separate medical staff for each hospital within a multi-hospital system'' (76 FR 65899). We stated this in order to point out the current language's potential ambiguity, not to propose a change in our interpretation of it. We continue to interpret the current CoP to require that each hospital, regardless of whether it is a part of a multi-hospital system, have a single and separate medical staff, as a matter of CMS policy.

Nevertheless, a number of comments supported a revision to the current requirement to allow for a single medical staff for hospitals in a multi-hospital system. Some commenters stated that it would be more efficient and save on resources for hospitals, particularly with regard to practitioner credentialing and privileging. Many commenters pointed to the potential for patient safety initiatives and quality of care improvements across multiple hospitals within a system if these programs were developed and overseen by a single medical staff. A few commenters expressed support for the idea only if it applied to smaller hospital systems confined to a more limited geographic area where many of the medical staff would be located close enough to be privileged at all of the hospitals in the system. These commenters were generally opposed to a single medical staff for large hospital systems that spanned multiple States.

A significant number of comments expressed opposition to the concept of a single medical staff responsible for the oversight of practitioners and the quality of patient care at multiple hospitals within a system. These commenters stated that such a proposal would undermine the fundamental idea behind a medical staff: self-governance. The commenters explained the concept of medical staff self-governance as one in which the medical staff is familiar with the practitioners whom it governs and is comprised of, understands the unique needs of the hospital in which the practitioners work, and ''can nimbly respond to health and safety issues that arise with respect to those patients and that hospital.'' The commenters pointed

out that medical staff self-governance is required by a hospital accrediting organization and is also mandated by some States and they questioned whether self-governance requirements would be met if a multi-hospital system was allowed to have a single medical staff overseeing an unlimited number of hospitals spread out over a wide geographic area and ''without the meaningful input of the physicians at each member hospital.'' Commenters further cited the negative impact that such a proposed change would have on peer review whereby the single medical staff at the headquarter hospital of the system (for example, a large urban tertiary care center) would review practitioners at a member hospital (for example, a rural hospital or a pediatric hospital) without having any first-hand knowledge or experience with the member hospital, its patient population, and its particular medical care needs. Finally, they pointed to the potential for conflict with current State peer review laws and regulations that such a change might create.

Response: We appreciate all of the comments received on this issue and apologize for any confusion that may have been caused by the ambiguous statement in the preamble to the proposed rule. We continue to agree with the commenters who opposed any changes to the current requirement that might allow for a single medical staff to oversee all hospitals within a multi-hospital system. We believe that the concerns of the commenters are valid, particularly with regard to medical staff self-governance, peer review, and accountability for patient care, and agree with the commenters that such a change in current requirements and interpretation could negatively impact the health and safety of patients. Therefore, as we previously stated in the preamble discussion of the proposed rule, we are retaining the current Medical staff requirement without revision and maintain our historical position that each hospital, even those in a multi-hospital systems, must have its own medical staff with the authority and responsibility for the quality of patient care provided in that hospital.

Comment: Some commenters supported keeping the hospital CoPs at the service/departmental level. Commenters suggested that the current departmental structure of the CoPs leads to a more fragmented and uncoordinated approach to delivering care; therefore, by arranging quality and safety requirements into systems of care, hospital staff would be likely to work as a team in developing care processes and systems that meet the requirements. Therefore, commenters urged CMS to move to a more system based approach for organizing the hospital CoPs. Other commenters suggested that CMS allow flexibility in organizational structure and requirements. Other commenters believed an organizational structure of the CoPs, reflecting areas of service, would be the most efficient; and in line with today's clinical management philosophy. The structure would enable the hospitals to improve care delivery and the quality and safety of patient care. Some commenters supported revising the overall organizational structure of the CoPs to condense regulations for departmental leadership into a single non-specific regulation. One commenter supported elimination of current specialty-department-specific leadership requirements into a single, non-specific CoP.

Response: We appreciate commenters' suggestions. These comments were outside the scope of this final rule, and we may consider these suggestions in future notice-and-comment rulemaking.

Medical Record Services (§ 482.24)

In the proposed rule (76 FR 65899), we considered modifying the current § 482.24(c)(2) to clarify the intent of the rule in situations where a patient has received a medical history and physical examination (H&P) by either a non-hospital practitioner or a practitioner with hospital privileges prior to the patient's hospital visit. We did not believe that the regulation should be amended, and specifically sought public comment on this issue. The following are responses to public comments received.

Comment: Several commenters supported our decision to not amend the current history and physical examination (H&P) provision, or its associated IG, contained under the Medical record services CoP at § 482.24(c)(2). Commenters stated that the language at § 482.24(c)(2) is clear and that it needs no further explanation. Other commenters agreed that it is appropriate to defer to the clinical judgment of the hospital staff to determine the extent of the necessary update.

Response: We appreciate the support of commenters on this issue and we agree that this provision does not need any further regulatory clarification. As we stated following our explanation of this provision and its IG in the proposed rule, we do not believe that the regulation should be amended.

Comment: Some commenters were concerned with what they saw as a rigid interpretation of the H&P requirement and stated that it causes unnecessary burden by not clarifying that H&Ps conducted within the 24 hours prior to an admission or registration are not necessary and that they should be left to the discretion of the clinician. One commenter recommended that CMS clarify its parameters for the timeframe related to an H&P update (for example, the value of performing updates to H&Ps that are completed shortly before a scheduled procedure requiring anesthesia services). In addition, it was suggested by a commenter that some surveyors continue to confuse the timeframe requirements for H&Ps with those for the pre-anesthesia evaluation. Another commenter suggested that CMS clarify this requirement to specify what constitutes an update of H&P to ensure that hospitals are complying appropriately with this requirement.

One commenter noted that the current H&P requirement allows only physicians to conduct H&Ps, which could result in delays in diagnosis and treatment in areas where there are not enough physicians. The commenter recommends that § 482.24 be modified to include PAs and APRNs. Another commenter was concerned that the wording of the current requirements may not fully recognize the ability of nurse practitioners to perform both the initial H&P and the subsequent reassessment of the patient after admission or registration, provided that the nurse practitioner is credentialed and privileged to perform these patient evaluations. Therefore, the commenter continued, future regulations and IGs should specifically clarify the authority of nurse practitioners to perform these evaluations. Another commenter stated that permitting an out-of-hospital H&P by a non-physician to substitute as the basis for hospital admission and treatment, instead of an H&P by a physician on the hospital medical staff, would create an unacceptable danger to patients since these non-physicians would be exempt from medical staff credentialing, privileging, and peer review. The commenter further stated that non-physicians often lack the education, training, experience, or licensure to perform a proper H&P for patients who are seriously ill. Another commenter stated that the following interpretation of this regulation needs to be clearly communicated to all: That a current H&P can be included in the patient's medical record if performed within 30 days prior to hospital admission; these H&Ps may be performed by any licensed independent practitioner (including Doctors of Podiatric Medicine) who is or is not a member of the medical staff, provided

that this does not substitute for proper clinical judgment related to updating the patient's status; and that, after the patient is admitted, all necessary H&Ps must be performed by a properly privileged and credentialed member of the medical staff as needed. One commenter stated there was confusion over the H&P update in that some physicians feel this rule compels them to do a full H&P (the commenter stated that this was the advice given by legal counsel), especially if the first one was not done by them.

One commenter supported the review of H&Ps conducted within the 30 days prior to hospitalization; however, the commenter encouraged CMS to allow organizations flexibility in documenting that review and that CMS should not prescribe the specific language or method to be used to indicate that the patient was re-examined and the results are noted (for example, ''the H&P was reviewed, the patient was examined, and 'no change' has occurred since the H&P was completed''). Another commenter was in agreement with the language of the H&P requirement, but noted if an update exam is needed it should be required by hospital policy rather than by CMS regulations. Some commenters noted that there is inconsistent application of H&P requirements by CMS and TJC. One commenter suggested that it would be very helpful if CMS would allow hospitals to address H&P requirements in the medical staff rules and regulations or policies.

Response: While we appreciate the various dissenting comments and opinions that we received on the H&P requirements, we must point out that many of these comments contained inaccuracies regarding both the requirements and the IGs. As such, the comments do not offer constructive criticism or evidence of a compelling need to revise the H&P requirements or the H&P IGs.

The intent behind this requirement has always rested firmly on the basic purpose of an H&P (and a subsequent update to an H&P)—that is, to determine whether there is anything in the patient's overall condition that would affect the planned course of the patient's treatment, such as an allergy to a medication that must be avoided, or a co-morbidity that requires certain additional interventions to reduce risk to the patient. To question ''the value of performing updates to H&Ps that are completed shortly before a scheduled procedure requiring anesthesia services'' is to question the value of performing an H&P in the first place. A patient's condition can change day to day, moment to moment. The update requirement ensures that any change in a patient's condition is noted and taken into consideration prior to a practitioner beginning a procedure or starting a treatment plan that may be affected by such a change. The H&P and its update give the practitioner as much information about the patient as he or she chooses to seek prior to beginning treatment. As written, the requirements and IGs allow the practitioner performing the update to exercise his or her independent clinical judgment with regard to how minimal, how focused, or how extensive the update to the H&P should be for a particular patient (71 FR 68676; *http://www.cms.gov/manuals/downloads/som107ap_a_hospitals.pdf*).

With regard to the comment that the requirements limit the performance of the H&P and its update to physicians, the requirements (under the Medical staff bylaws provisions at §§ 482.22(c)(5)(i)–(ii)) have always been explicit that other qualified licensed individuals may perform these evaluations. Other qualified licensed individuals are those licensed practitioners (such as APRNs and PAs) who are permitted by their State scope of practice laws or regulations to conduct a history and physical examination (and any updates to it), and who are also formally authorized by the hospital to conduct an H&P and its updates. Therefore, we do not agree that we need to clarify that these types of practitioners can perform these duties.

Conversely, there was the comment that posited the idea that allowing these types of practitioners to perform H&Ps and updates poses an ''unacceptable danger to patients'' since these nonphysician practitioners ''often lack the education, training, experience, or licensure to perform a proper H&P for patients who are seriously ill.'' The commenter also stated that non-physician practitioners who perform H&Ps prior to admission (for example, as part of a primary care practice) and who are not on the medical staff would be exempt from medical staff credentialing, privileging, and peer review. While the fact that non-medical staff APRNs and PAs are exempt from medical staff peer review is certainly true (and, for that matter, so it would also be for non-medical staff physicians), it cannot be assumed that the quality of the H&Ps would be any less than those performed by medical staff APRNs, PAs, and physicians. However, the practitioner responsible for the care of the patient always has the option to perform a new H&P if he or she feels that the H&P done prior to admission or registration by the patient's primary practitioner is less than adequate.

Finally, the language in the IGs regarding what a practitioner might write in the medical record for a patient requiring an update to his or her H&P, but having no changes in his or her condition, is not intended to be prescriptive. It is provided as merely an example.

Physical Environment (§ 482.41)

Currently, hospitals are required to meet the standards of the 2000 edition of the Life Safety Code (LSC). In the proposed rule (76 FR 65899–65900), we noted the 2012 LSC edition was expected for release in fall 2011, and based on the 2012 edition's content we would decide whether it or another more recent edition was appropriate for incorporation into regulations for hospitals and other affected providers and suppliers. We also noted any regulatory changes would be addressed through separate notice-and-comment rulemaking; and asked the public for their comments in regard to LSC (76 FR 65900). The 2012 LSC has been subsequently released since the publication of this proposed rule.

Comment: Many commenters recommended the adoption of the Life Safety Code (LSC) (2012 edition) in Physical environment § 482.41. Many commenters also suggested that CMS could ensure continued relevance of its LSC requirements by mandating that hospitals comply with the most current LSC requirements, rather than reference a specific edition of the LSC as it has previously done. A few commenters urged CMS to adopt the 2009 edition of the LSC. One commenter suggested CMS adopt the version of the LSC that the State Fire Marshal is using for that particular State. One commenter stated at the time CMS considers updating the LSC, that both the 2009 International Building Code and International Fire Code be considered as an allowable means of meeting the fire and life safety requirements at § 482.41. A few commenters noted that currently multiple authorities have jurisdiction over hospitals and may use different versions of the LSC, which creates substantial burden on hospitals and confusion in the field. Some commenters also recommended that the Health Care Facilities Code (National Fire Protection Association (NFPA) 99–2012) should also be adopted. One commenter asked whether a fire alarm system installed in 2000 would have to be in compliance with the maintenance, inspection, and testing rules of the 2000 or the 2012 edition of the NFPA 72.

Response: We appreciate commenters' suggestions regarding the LSC regulations set out under our ''Physical environment'' CoP at § 482.41. Suggestions received were outside the scope of this final rule and will be considered through separate notice-and-comment rulemaking in a LSC omnibus rule, targeted for publication in the near future.

Public Comments Regarding Possible Areas for Future Rulemaking

The proposed rule (76 FR 65904) solicited any additional public comments on the hospital CoPs which were beyond that of the proposed provisions. Many commenters provided public comments that were outside the scope of this final rule, and below is a summary of responses to those public comments received.

Interpretive Guidelines (IGs)

One commenter suggested that CMS should provide easy access to up-to-date hospital CoPs and IGs on the CMS Web site (instead of rewriting hospital CoPs in another format), and support a more robust search engine for users. Other commenters suggested that CMS revise the way in which it develops changes to IGs to allow for meaningful stakeholder and subject matter expert input, making the process more transparent. Other commenters suggested that accrediting bodies should have an opportunity to review and provide comment on new and modified IGs before they are released in a Survey and Certification Director's letter. Another commenter suggested that the IGs should be reviewed annually, at a minimum, to allow for meaningful input. Commenters believed there should be a complete review of the CoP's IGs, as they are believed to have become overly wordy, burdensome, and subject to inconsistent interpretation (for example, the new IG on anesthesia includes analgesia which goes beyond the limits of the regulation, etc.). One commenter suggested that there is a need for the IGs to be very explicit regarding processes for credentialing and privileging non-licensed independent practitioners. In addition, commenters encouraged CMS to conduct more robust training for State survey personnel to ensure consistent interpretations of the IGs during surveys.

Immediate Jeopardy

Commenters urged that CMS further define immediate jeopardy, as well as the process in place to apply immediate jeopardy to value-based purchasing. Additionally, commenters suggested that CMS should explain the process in place to guarantee that consistent standards, across the nation, will be used to evaluate situations in which immediate jeopardy is suspected.

Privacy Standards

Commenters noted the comprehensive HIPAA standards, not the general CoP provisions, provide the appropriate basis for protecting the privacy and security of patient medical information without inhibiting the coordination of patient care. Commenters further recommended that CMS eliminate the CoP obligations for medical records confidentiality for providers, and instead rely on the Office of Civil Right's interpretation, oversight and enforcement of the compliance obligations under the HIPAA privacy and security standards.

Nuclear Medicine

One commenter suggested modifications to Nuclear medicine at § 482.53(b)(1) to remove the word ''direct'' to reflect the delegation authority of the authorized user. Additionally, the commenter suggested the IGs regarding § 482.53(b)(1) should be enhanced focusing on the term ''authorized user'' (for example, CMS to allow the authorized user be given the authority, as noted and consistent with the Nuclear Regulatory Commission guidelines, to delegate specific tasks, as they are best suited for determining tasks that supervised individuals can perform and the degree of supervision required; further the authorized user should put policies in place to clarify the specific tasks delegated and the supervision and certification necessary for each), certification of uniform competencies, radiopharmaceutical preparation qualifications, relevant practice standards, and certification assessments rather than layering staff. One commenter suggested that the Nuclear medicine CoP and IGs be updated in the future rulemaking.

Radiologic Services

Commenters suggested that patient-directed care is not adequately recognized in the CoPs, and that CMS should amend Radiologic services at § 482.26(b)(4) to be consistent with State law for those services permitted to be self-referred by hospital patients.

Special Provisions Applying to Psychiatric Hospitals

One commenter suggested that CMS review the CoP at § 482.60, Special provisions applying to psychiatric hospitals. Specifically, the commenter suggested modifications to the current provisions at § 482.61(b) stating more flexibility for professional judgment regarding the breadth and depth of assessments should be allowed through the development of hospital-specific policies rather than requirements of CoPs; § 482.61(c) stating there are other ways to assure that patients are receiving appropriate treatment modalities with sufficient frequency and intensity to justify inpatient treatment than are currently required by the CoPs; and § 482.62(a) suggesting that the provision of interdisciplinary treatment can be accomplished in many ways and that hospitals should be encouraged to provide that treatment in the most flexible and efficient way possible, based on individual patient needs and hospital policy.

Emergency Services

One commenter suggested telemedicine modifications to § 482.55(b)(2), Emergency services, to add ''available in-person or by video conferencing.'' The commenter also suggested incorporating a new provision to allow hospitals to provide access for stroke care through telemedicine at § 482.55 to state ''there must be adequate medical personnel, available in-person or by video conferencing, qualified in ischemic stroke diagnosis to order appropriate treatment including timely thrombolytic therapy where appropriate.''

Intensive and Critical Care Services

One commenter suggested adding a new CoP at § 482.58 for intensive and critical care services, to be modeled on the emergency services provision at § 482.55.

Discharge Planning

One commenter recommended revisions at § 482.43(b)(3), Discharge planning, that would include the patient's risk of readmission for the diagnosis by adding text that states ''patient's readmission for related care and * * *''.

Regulations Governing Graduate Medical Education

One commenter believed the rules lead to additional cost and make it more difficult to administer responsive, quality graduate medical education programs, especially in regards to integrated healthcare systems.

Regulations Governing Quality Measurement

One commenter stated that over the years there has been a proliferation of quality measures across provider types; therefore, this commenter suggested that CMS consider a periodic review of all

measures to ensure that there is as little administrative burden as possible, that the measures are compatible from entity to entity, and that the measures move the program in the same direction rather than splinter providers' focus.

Electronic Health Records (EHRs)

Commenters suggested CMS consider how to incorporate EHRs into the CoPs and IGs.

Payment

Several commenters urged CMS to reevaluate payment. A few commenters stated they did not understand the rationale for CMS to impose stricter supervision regulations under the Outpatient Prospective Payment System (OPPS) rule, in that direct supervision is not a requirement for inpatient services when the patient is presumably more acutely ill, so to impose director supervision for outpatient therapeutic services is not clinically sensible.

Future Rulemaking Affecting CoPs

One commenter recommended that CMS provide guidance about how future rulemakings affecting CoPs or other programs will increasingly seek to incentivize evidence-based care processes that integrate patients and families into care decision-making and clinical workflow.

Response: Thank you for the suggestions. These comments were outside the scope of this final rule, and we may consider these suggestions in future notice-and-comment rulemaking and/or through the IGs.

Food and Dietetic Services

Comment: One commenter suggested CMS consider revising the requirement for a paper-based therapeutic diet manual, in Food and dietetic services § 482.28, and allow organizations a more contemporary approach for staying current with nutritional guidelines (for example, that facilities should be allowed the flexibility to utilize knowledge-based information in a variety of forms as a means of staying current, as opposed to utilizing a hard-copy manual, which does not allow organizations to keep up with rapid changes in the field.).

Response: Currently, the CoP at § 482.28(b)(3) does not specifically require a ''paper-based'' therapeutic diet manual. The current CoP at § 482.28(b)(3) states, ''A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.'' We will take this comment into consideration for future rulemaking.

III. Provisions of the Final Rule

In this final rule, we are adopting the provisions of the October 24, 2011 proposed rule (76 FR 65891) with the following revisions, which will apply to hospitals and CAHs, based on public comments:

Governing Body (§ 482.12)

- In response to public comments, we are revising the introductory text to add a requirement at § 482.12 that the governing body must include a member, or members, of the hospital's medical staff.

Patient's Rights (§ 482.13)

- We are revising paragraph (g)(2) to delete the phrase, ''report to CMS,'' and to clarify that for those deaths related only to soft, two-point wrist restraints the hospital staff must record the information regarding the patient's death in an internal log or other system.
- We are revising paragraph (g)(2) and (g)(4) to clarify that the log is internal to the hospital.
- We are revising paragraph (g)(3) to specify that ''The staff must document in the patient's medical record the date and time the death was: (i) Reported to CMS for deaths described in paragraph (g)(1); or (ii) Recorded in the internal log or other system for deaths described in paragraph (g)(2).''
- We are revising paragraph (g)(4)(ii) to specify that each entry must document the patient's name, date of birth, date of death, ''name of attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c),'' medical record number, and primary diagnosis(es).

Medical Staff (§ 482.22)

- Remove proposed paragraph (a)(5).
- Revising paragraph (a) to change the title of the standard from ''Composition of medical staff'' to ''Eligibility and process for appointment to medical staff,'' and require that the medical staff must include doctors of medicine or osteopathy, but may also include other categories of non-physician practitioners determined as eligible for appointment by the governing body in accordance with State law, including scope-of-practice laws.
- Revise paragraph (a)(2) to require that the medical staff must examine the credentials of ''all'' eligible candidates and then make recommendations on medical staff membership to the governing body, and require that a candidate who has been recommended by the medical staff and appointed by the governing body be subject to all medical staff bylaws, rules, and regulations, in addition to the requirements contained in § 482.22.

Nursing Services (§ 482.23)

- Revise paragraph (c)(1)(i) to clarify that drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under § 482.12(c) only if such practitioners are acting in accordance with State law, including scope- of-practice laws, ''hospital policies, and medical staff bylaws, rules, and regulations.''
- Revise paragraph (c)(3)(iii) to clarify that orders for drugs and biologicals may be documented and signed by other practitioners not specified under § 482.12(c) only if such practitioners are acting in accordance with State law, including scope- of- practice laws, ''hospital policies, and medical staff bylaws, rules, and regulations.''
- Revise paragraphs (c)(6)(i)(A) and (c)(6)(ii)(A) to change ''assure'' to ''ensure.''
- Revise paragraphs (c)(6)(i)(D) and (c)(6)(ii)(D) to clarify that the hospital must have policies and procedures in place to ''address'' the security of the medication(s) for each patient and to document the administration of each medication.
- Revise paragraphs (c)(6)(i)(E) and (c)(6)(ii)(E) to provide that the hospital must document the administration of medication ''as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.''

Medical Record Services (§ 482.24)

- Revise paragraphs (c)(2) and (c)(3)(iv) to remove the reference to § 482.12(c) and to clarify that all orders, including verbal orders and standing orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient ''only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.''
- Revise paragraphs (c)(3)(i) and (c)(3)(iii) by removing proposed language ''in consultation with.''

CAHs

- We have removed the definition for direct services at § 485.602, we have removed the reference to ''direct services'' at §§ 485.623(a) and 485.635(a)(3)(i).
- In § 485.604(a), we revised the definition to provide that a clinical nurse specialist is a registered nurse and is licensed to practice nursing in the

State in which the clinical nurse specialist services are performed, ''in accordance with State nurse licensing laws and regulations;'' and holds ''a master's or doctoral level'' degree in a defined clinical area of nursing from an accredited educational institution.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-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). Responses to comments received for this section can be found below in the Regulatory Impacts section (V).

According to CMS, there are about 4,900 hospitals (not including CAHs) that are certified by Medicare. We will use those figures to determine the burden for this rule. In addition, throughout this section, we estimate costs based on average hourly wages for different healthcare providers and attorneys. Unless indicated otherwise, we obtained these average hourly wages from the United States Bureau of Labor Statistics' ''May 2010 National Occupational Employment and Wage Estimates United States'' (*www.bls.gov/oes/current/oes_nat.htm accessed on September 28, 2011*). We also added 30 percent to the indicated average hourly wage to compensate for overhead and fringe benefits.

A. ICRs Regarding Condition of Participation: Patient's Rights (§ 482.13)

Section 482.13(g) removes the current requirement for hospitals to notify CMS by telephone no later than the close of business the next business day following knowledge of a patient's death for patients who die when no seclusion has been used and the only restraints used on the patient were soft, non-rigid, cloth-like materials, which were applied exclusively to the patient's wrist(s). This requirement includes patients who died within 24 hours of having been removed from these types of restraints. In those cases, the hospital must report to CMS by recording in a log or other system the information required at § 482.13(g)(2)(i) and (ii). We noted this change only for deaths where the patient died while either in soft two-point wrist(s) restraints or within 24 hours of having been removed from soft two-point wrist(s) restraints provided that: (a) There is no reason to believe the death was caused by those restraints, (b) that those were the only restraints used, and (c) that no seclusion was used.

We believe that we previously underestimated the burden and costs associated with the current reporting requirement. After discussions with other CMS staff, we now believe that this reporting would be done by a nurse rather than a clerical person and that there are substantially more deaths that occurred to patients while they were in soft, non-rigid, cloth-like material, which were applied exclusively to a patient's wrist(s), or within 24 hours of being removed from this type of restraints.

We will be revising the current burden estimates for OMB control number 0938–0328 to reflect the burden estimated to be associated with the current regulations and would adjust for any burden reductions resulting from this provision once the current rule is finalized. For a more detailed discussion of estimated burden and cost savings, please see the Regulatory Impact Analysis section of this rule.

B. ICRs Regarding Condition of Participation: Nursing Services (§ 482.23)

The current hospital CoPs require that hospitals ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient (42 CFR 482.23(b)(4)). Section 482.23(b)(4) allows those hospitals that have interdisciplinary care plans (ICPs) to have their nursing care plans developed and kept current as part of the hospital's ICPs. Based on our experience with hospitals, a nurse would develop and maintain the nursing care plan for each patient. The nurse would also be responsible for identifying the sections of each nursing care plan that needed to be integrated into the hospital's ICP and transferring that information into the ICP. Thus, allowing hospitals to include the nursing care plan in the ICP for each patient would save the nurse the time she or he is currently spending identifying and transferring information from the separate nursing care plan into the ICP and maintaining the separate nursing care plan.

In the currently approved OMB control number 0938–0328, we indicated that the creation and maintenance of a nursing care plan constituted a usual and customary business practice and did not assign a burden for this requirement in accordance with 5 CFR § 1320.3(b)(2). Since completing that package, we have reconsidered our estimate of that analysis. While we continue to believe that creating and maintaining a health care plan for each patient is a usual and customary practice for hospitals, we do not believe that is usual and customary for hospitals to develop and maintain a separate nursing care plan when they also develop and maintain an ICP.

We will be revising the current burden estimates for OMB control number 0938–0328 to reflect the burden estimated to be associated with the current regulations and would adjust for any burden reductions resulting from this provision once the current rule finalized. For a more detailed discussion of estimated burden and cost savings, please see the Regulatory Impact Analysis section of this rule.

C. ICRs Regarding Condition of Participation: Medical Record Services (§ 482.24)

In the currently approved OMB control number 0938–0328, we indicated that most of the patient-related activities, such as authentication of verbal orders and using standing orders, constituted a usual and customary business practice and did not assign a burden for this requirement in accordance with 5 CFR 1320.3(b)(2). However, we have reconsidered our analysis. We believe that the authentication of verbal orders should be governed by State law and not mandated by the Federal government. In addition, while writing orders is generally a usual and customary business practice in hospitals, hospitals can also choose how those orders will be conveyed. We believe that some hospitals are not currently using standing orders as often as they would choose to due to our CoPs. Therefore, by allowing authentication of verbal orders to be governed by State law and expanding the use of standing orders, we believe that this would result in a burden reduction.

We will be revising the current burden estimates for OMB control number 0938–0328 to reflect the burden estimated to be associated with the

current regulations and would adjust for any burden reductions resulting from this provision once the current rule is finalized. For a more detailed discussion of estimated burden and cost savings, please see the Regulatory Impact Analysis section of this rule.

D. ICRs Regarding Condition of Participation: Infection Control (§ 482.42)

The current hospital CoPs require that ''the infection control officer or officers must maintain a log of incidents related to infections and communicable disease'' (42 CFR 482.42(a)(2)). In this final rule, we are eliminating this requirement for keeping a dedicated log of incidents related to infections and communicable diseases, proposing instead to allow hospitals flexibility in their approach to the tracking and surveillance of infections.

In the currently approved OMB control number 0938–0328, we did not assign a burden for creating and maintaining this log. However, we have reconsidered our analysis. We believe there are many alternatives available that present an even greater opportunity to monitor and analyze infection control activities than keeping a log as currently required by the CoPs. In addition, we believe that the log is a format that hospitals are using only because of the CMS requirement and that they are producing data in this fashion in addition to the format they are using for their own purposes. Thus, while identifying and monitoring infections that patient have during hospitalization would be usual and customary for hospitals, we believe that requiring hospitals to keep a log rather than decide how they could best keep track of this information is burdensome for hospitals.

We will be revising the current burden estimates for OMB control number 0938–0328 to reflect the burden estimated to be associated with the current regulations and will adjust for any burden reductions resulting from this provision once the current rule is finalized. For a more detailed discussion of estimated burden and cost savings, please see the Regulatory Impact Analysis section of this rule.

E. ICRs Regarding Condition of Participation: Transplant Center Process Requirements—Organ Recovery and Receipt (§ 482.92)

In this final rule, we are removing § 482.92(a) entirely. The elimination of this section removes the burden on the part of transplant centers by eliminating a requirement to review and compare blood type and other vital data before organ recovery takes place.

In the currently approved OMB control number 0938–1069, we indicated that the verification by the transplant hospital recovery physician when the recipient was known constituted a usual and customary business practice and did not assign a burden for this requirement in accordance with 5 CFR 1320.3(b)(2). However, since that PRA package was approved by OMB, several members of the transplant community have repeatedly told CMS that this verification was unnecessary and burdensome because OPOs already perform this type of verification prior to organ recovery in accordance with § 486.344(d)(2)(ii). Therefore, we have reconsidered our estimate of the burden for this requirement.

We will be revising the current burden estimates for OMB control number 0938–0328 to reflect the burden estimated to be associated with the current regulations and would adjust for any burden reductions resulting from this provision once the current rule is finalized. For a more detailed discussion of estimated burden and cost savings, please see the Regulatory Impact Analysis section of this rule.

V. Regulatory Impacts

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this rulemaking as required by Executive Orders 12866 (September 1993) and 13563 (January 2011). Executive Orders 12866 and 13563 direct 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. A Regulatory Impact Analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any one year). This final rule is an ''economically'' significant regulatory action under section 3(f)(1) of Executive Order 12866. Accordingly, the Office of Management and Budget (OMB) has reviewed this final rule.

2. Statement of Need

In Executive Order 13563, the President recognized the importance of a streamlined, effective, efficient regulatory framework designed to promote economic growth, innovation, job-creation, and competitiveness. To achieve a more robust and effective regulatory framework, the President has directed each executive agency to establish a plan for ongoing retrospective review of existing significant regulations to identify those rules that can be eliminated as obsolete, unnecessary, burdensome, or counterproductive or that can be modified to be more effective, efficient, flexible, and streamlined. Consistent with this directive, CMS conducted a retrospective review of the CoPs it imposes on hospitals to remove or revise obsolete, unnecessary, or burdensome provisions. The goal of the retrospective review was to identify opportunities to reduce system costs by removing obsolete or burdensome requirements while maintaining patient care and outcomes.

CMS has not reviewed the entire set of CoPs for Hospitals in many years. These requirements have grown over time and, while often revised, have not been subject to a complete review. CMS staffs as well as CMS stakeholders, including TJC, the American Medical Association, the AHA, and many others, have identified problematic requirements over the years. Accordingly, we decided to conduct a retrospective review of the CoPs imposed on hospitals and to remove or revise obsolete, unnecessary, or burdensome provisions, and to increase regulatory flexibility while identifying and adding opportunities to improve patient care and outcomes. We analyzed all potential reforms and revisions of the CoPs for both the costs and the benefits that they would bring to hospitals and CAHs. Based on our analysis, we decided to pursue those regulatory revisions that would reflect the substantial advances made in healthcare delivery and that would benefit hospitals and CAHs through cost savings.

We received hundreds of substantive comments supporting our choice of provisions for reform, the specific reforms we proposed, and the general conclusions we had reached as to likely importance or magnitude of potential savings. Public comments and corresponding responses regarding the Collection of Information Requirements and the Regulatory Impacts section can be found below:

Comment: We received numerous comments regarding the paperwork or information collection requirement (ICR) section and the regulatory impact section from health care institutions and their national organizations, health care

providers and their national organizations, health care advocacy organizations, as well as others. Most of these commenters were supportive of our efforts to reduce burden from the hospital CoPs, especially those that did not contribute to quality patient care, and our estimates of the resulting savings. Many commenters, especially health care providers stated that removing these burdensome provisions would actually contribute to quality of care for patients, allow them more time for direct patient care, and to better utilize their resources.

Response: We would like to thank the commenters for their support of our efforts to reduce the burden from the hospital CoPs.

Comment: We received a few comments that questioned our estimate of 882,000 occurrences of patients who died while either in, or within 24 hours of being removed from, soft, wrist only restraints. One commenter noted that we did not account for the time that would be required to perform the log entries.

Response: We agree with the commenters. Since publication of the proposed rule, we have reviewed some new data and agree that the estimate of 882,000 occurrences is likely overstated. We have revised our estimate below. We did not account for the time it would take to complete a log entry in the proposed rule. We believe that hospitals would likely choose the most efficient manner in which to keep this log. For example, they may have a nurse complete these entries as a group or develop a process for transferring the information electronically to a log. We continue to believe that removing the requirement to report these deaths to CMS would result in the savings we estimated in the proposed rule, of approximately 15 minutes for each entry.

Comment: We received a few comments that questioned our estimate of $330 million in savings from the proposed revisions in § 482.22. Commenters indicated that they wanted further clarification, that they believed the estimate was in error, and questioned using the difference between a physician and non-physician's salary.

Response: We disagree with the commenters. In fact, we believe that the savings might be much greater. Our detailed estimate is located in the regulatory impact section (below). As we noted, we only estimated the savings for inpatient hospital stays. We did not estimate the savings for the approximately 620,000 annual outpatient visits. Therefore, we have not modified our estimate.

Very few of these comments provided any criticism of, and no comments offered technical information to improve, our estimates of potential savings. Accordingly, we have not changed our estimates of potential and likely savings. We plan to evaluate cost savings and other potential impacts in the future, including changes that might increase or decrease patient safety or health, based on actual changes implemented by hospitals and CAHs. It is important to understand that our estimates are necessarily uncertain because they depend largely on changes that hospitals and their medical staffs could decide to adopt or not adopt on a case-by-case basis. Some estimates also depend upon the future decisions by States to change their laws and regulations covering the scope of practice of non-physician practitioners.

Comment: A number of commenters noted that the ability of hospitals and CAHs to implement these reforms would depend upon our revising the current interpretative guidelines for the hospital and CAH CoPs.

Response: As we have discussed elsewhere in this rule, we will be issuing guidance on how hospitals and CAHs can implement the changes in this final rule shortly.

3. Summary of Impacts

These reductions in process and procedure requirements detailed in this final rule may allow hospitals and CAHs to redirect staff resources to areas of higher priority that they view as producing greater benefit to patients. They could also enhance hospitals' ability to flexibly deploy resources and reengineer internal processes. We present a summary of these cost-reducing changes in Table 2.

TABLE 1—SECTION-BY-SECTION SUMMARY OF COST SAVINGS TO HOSPITALS AND CAHS

[2012 Dollars; entries rounded to nearest $100K if under $50M and to nearest $10M if higher]

Regulatory area	Section	Annual savings ($K)	Five year savings ($K)
Patient's Rights—Death Notice Soft Restraints	482.13	$5,100	$25,500
Medical Staff	482.22	330,000	1,650,000
Nursing Services—Care Plan	482.23	110,000	550,000
Medical Record Services—Authentication	482.24	80,000	400,000
Medical Record Services—Standing Orders	482.24	90,000	450,000
Infection Control—eliminate log	482.42	6,600	33,000
Outpatient Services	482.54	300,000	1,500,000
Transplant Organ Recovery	482.92	200	1,000
CAH Provision of Services	485.635	15,800	79,000
Total	.....	937,700	4,688,500

Some of these savings come simply from reductions in process requirements and reporting. The changes in the area of medical staffing and several other areas would allow hospitals more flexibility in hiring and staffing decisions, including use of part-time and contract staff, to provide patient services efficiently and effectively. Total national hospital spending is about nine hundred billion dollars a year and about half of this is spent on staff compensation (source: AHA Hospital Statistics). Thus, the potential magnitude of the efficiencies that could be achieved is very large.

Clearly, the amount of savings actually realized through these reforms will depend on the individual decisions of about 6,100 hospitals (including CAHs), over time. We cannot predict the extent or speed of these elective changes. Other factors, such as impending physician shortages and the growing use of other practitioners to perform many physician functions will play a role as will State decisions on laws delineating scope of practice.

Furthermore, for the requirements that we are modifying or deleting, we

are not aware of any information suggesting that these changes would create consequential risks for patients. In other words, we do not believe that any eliminated requirement in this final rule has saved lives in recent decades. In public comments, several commenters raised important questions regarding patient safety. We reviewed all of those comments with great care; however, in our review of these comments we could not identity a single comment that provided any empirical or scientific evidence, or even plausible arguments, that any proposed reform threatened patient safety. The mere possibility of harm, unsupported by evidence, does not justify retention of regulatory provisions that are based on mere supposition or hypothetical arguments. Under the standards of EO 12866 and EO 13563, a regulatory requirement must be justified by a showing of need. No comments we received demonstrated any need to retain the particular provisions we proposed to eliminate or reform.

4. Anticipated Impacts

There are about 4,900 hospitals and 1,200 CAHs that are certified by Medicare. According to CASPER (February 1, 2012), there are 6,180 hospitals. However, that number includes religious non-medical health care institutions (RNHCIs), which are not included in this rule, and critical access hospitals (CAHs), which are not included in the hospital provisions. In addition, according to CMS, there are about 107 CAHs with distinct part units (DPUs) that must comply with the hospital CoPs. Therefore, we have analyzed the hospital provision for 4,900 hospitals (6,180 total hospitals—18 RNHCIs—1,330 CAHs + 107 CAHs with DPUs = 4,939 or about 4,900 hospitals). For the CAHs, we analyzed the burden for 1,200 CAHs (1,330 CAHs –107 CAHs with DPUs that are analyzed with the hospitals = 1,223 or about 1,200 CAHs). Thus, in the final rule, we used these figures to estimate the potential impacts of this rule. In addition, we used the following average hourly wages for nurses and physicians respectively: $45 and $124 (BLS Wage Data by Area and Occupation, including both hourly wages and fringe benefits, at *http://www.bls.gov/bls/blswage.htm* and *http://www.bls.gov/ncs/ect/*). We received no comments suggesting a change in these hourly wage assumptions.

The analysis below overlaps with the Collection of Information Requirements section for many individual items. That section contains more technical and legal detail as appropriate under the Paperwork Reduction Act, but that is not normally necessary in a Regulatory Impact Analysis. Readers may wish to consult both sections on some topics.

Death Notices for Soft Restraints (Patient's Rights § 482.13)

In this final rule, we are removing the current requirement for hospitals to notify CMS by telephone no later than the close of business the next business day following knowledge of a patient's death for patients who die when no seclusion has been used and the only restraints used on the patient were soft, non-rigid, cloth-like materials, which were applied exclusively to the patient's wrists. Reporting for patients who died within 24 hours of having been removed from these types of restraints is also removed.

In the proposed rule, we estimated that full reporting of all such instances would result in 882,000 occurrences. This is much greater than the assumption that originally established this reporting requirement in the final rule (71 FR 71425). However, since the requirements have come into effect, we believe our initial estimate was low. In addition, we also received comments questioning the estimate of 882,000 occurrences. We conducted further research and have decided that our estimate in the proposed rule was overstated. Therefore, we have revised our savings estimate below.

In addition, the assumption in the 2006 final rule was that administrative support personnel would carry out these functions. Based on our experience with hospitals, this assumption is incorrect. A registered nurse would be the more appropriate staff member to make the call and to enter the information into a patient's medical record. The difference between the average hourly wage for a clerical person and a registered nurse ($18.88 per hour versus $45 per hour) would account for a significant discrepancy in estimated burden between the 2006 final rule and this proposed rule. Similar to the 2006 rule, we still estimate that it would take about fifteen minutes (or .25 hours) to comply with this requirement for each occurrence. The estimate of the time is also based on our experiences with hospitals as well as feedback from stakeholders that indicates that this estimate is reasonable.

According to the United States Agency for Healthcare Research and Quality (AHRQ), there were 757,841, or about 758,000, in-hospital deaths in 2009 (*http://hcupnet.ahrq.gov/HCUpnet.jsp* accessed February 10, 2010). There are many reasons for a patient to be physically restrained. According to Evans and FitzGerald, two of the most often cited reasons for restraining patients were treatment-related and for safety reasons (Evans, D. and FitzGerald, M, *Reasons for physically restraining patient and residents: a systematic review and content analysis*, International Journal of Nursing Studies 39 (2002), pp. 735–743). The treatment-related reasons include preventing patients from disturbing medical devices, such as endotracheal tubes, intravenous lines (IVs), nasogastric or feeding tubes, urinary catheters, wounds, dressings, and sutures (Evans and FitzGerald, p. 738). Patients might also be restrained for their own safety, such as when patients have impaired judgment or might harm themselves. We believe that many of the patients who die in the hospital are those who were seriously ill or injured and whose treatment likely involved medically necessary devices (such as endotracheal tubes and respirators due to post-operative respiratory failure) or those who may have suffered from impaired cognition and judgment due to their conditions. Thus, we believe that many of these patients may have been restrained at the time of, or within 24 hours of, their deaths so that medically necessary treatments could be carried out in the most safe and effective manner. Thus, we estimate that 60 percent of the 758,000 in-hospital deaths, or 454,800 deaths, would have been reported to CMS.

Similar to the 2006 rule, we still estimate that it would take about fifteen minutes (or .25 hours) to comply with this requirement for each occurrence. We are also basing this timesaving estimate on our experiences with hospitals as well as feedback from stakeholders that indicated that this estimate was reasonable. Therefore, we estimate that this reduction in burden would reduce each hospital's burden hours by about 23 hours (454,800 occurrences × .25 hours ÷ 4,900 = 23.20 or about 23 hours) each year valued at $45 for each hour for an average annual savings of $1,035 (23 hours × $45 hourly wage for a nurse = $1,035). Thus, we estimate that for all 4,900 hospitals this would result in a savings of about $5,116,500 (454,800 occurrences × $45 × .25 hours = $5,116,500 estimated savings).

Medical Staff (§ 482.22)

Our changes and clarifications regarding medical staff and privileging allow hospitals to substitute and rearrange actual delivery of care. In particular, use of Advanced Practice Nurse Practitioners (APRNs) and

Physician Assistants (PAs) in lieu of higher-paid physicians could provide immediate savings to hospitals. While we have no precise basis for calculating potential savings, we feel confident that our estimates reflect a reasonable approach to hospital cost savings. However, much will depend on the future staffing and management decisions that individual hospitals make. For example, the savings that we believe that hospitals will realize from the changes to the Medical staff CoP will depend on the extent to which hospitals take advantage of the regulatory flexibility that the new requirements afford. Those hospitals that view these changes as a means to be more inclusive of non-physician practitioners on their medical staffs would most likely reap the most benefits.

With that said, we also believe that an interdisciplinary team approach to patient care is the best model for hospital patients. Within this model, non-physician practitioners have proven themselves capable of handling many common patient complaints, initial patient work-up and follow-up, patient education and counseling, and the specific aspects of patient care for which they have been educated and trained. Physicians, as leaders of these teams due to their more extensive training and expertise, are then able to more fully turn their attention to more complicated patient problems. In this way, non-physician medical staff members allow physicians to more efficiently and effectively manage their time so that these physician leaders can focus on more medically complex patients. It is within this context of efficient and effective care delivery by physicians and non-physician practitioners working collaboratively that we have based our estimates. For purposes of this analysis, we have reached an estimate of $330 million in savings using the following assumptions, which are based on our experience with hospitals:

- All hospitals are able, under State scope-of-practice laws (that is, 4,900 hospitals), and one third of these are willing (that is, 1,617), to structure their medical staffs in this manner;
- There are on average 7,000 inpatient hospital stays per hospital per year (from AHA Hospital Statistics);
- The average hospital stay is about 5 days (per AHA statistics);
- On average, each patient receives approximately 75 minutes (1.25 hours) of a physician's time (for example, in-person visits/assessments, including patient and family education; review of patient lab and other diagnostic test results; documentation of orders, progress notes, and other entries in the medical record; performance of minor procedures; and discussion of the patient's condition with other staff) during an average 5-day stay;
- At a minimum, 33 percent of this physician per patient time would now be covered by non-physician practitioners (for example, APRNs and PAs); and
- There is an average salary difference of $71 an hour between physicians and these practitioners.

The resulting savings estimate of about $330 million annually (1,617 hospitals × 7,000 inpatient hospital stays × 1.25 hours of physician/non-physician practitioner time × $71 per hourly wage difference × 33 percent of physician time with patients covered by non-physician practitioners) could obviously be much higher or lower if any of the parameters above changed. Additionally, we have restricted our estimates to inpatient hospital stays and we did not include a discussion of the approximately 620,000,000 annual hospital outpatient visits (AHA Hospital Statistics) and the impact that these changes could have on staffing costs for hospitals in light of this number. Thus, many reasonable variations of our assumptions would lead to a similar magnitude of savings.

We received several comments criticizing this lack of precision in these estimates. One of these suggested additional consultation with stakeholders. We agree with those commenters that better estimates would be desirable. However, no commenters provided any information showing that there would be costs not accounted for in these estimates (for example, reductions in patient safety), or provided any information showing that these estimates were either too low or too high. Since these estimates depend overwhelmingly on future State decisions regarding non-physician practitioner practice limitations, and on the independent decisions of hospital governing boards and medical staffs, we have no basis for a revision in this final rule. We point out, however, that our initial savings estimates were quite conservative when viewed against the potential ability of medical staffs to economize by delegation to non-physician practitioners acting within the scope of the licenses already granted by many States.

The most obvious example of this potential ability to economize by delegation would be the surgeon who uses the services of available hospital APRNs and PAs to see and provide post-operative care and management of his or her patients, freeing the surgeon to focus on procedures and surgeries in the operating room. The surgeon still leads the team, but this model allows for both the surgeon and the APRN or PA to practice to the full extent of their training and experience and to effectively manage their time regarding patient care, ultimately benefitting each patient in the process. Some hospitals have already realized that having a dedicated APRN/PA service available to physicians can reduce overall costs by allowing for the more effective management and care of most patients during their hospital stay, from admission through discharge. In listening to stakeholders, we realized that the revisions to the Medical staff CoP that we have finalized here are necessary to ensure that all hospitals have the opportunities for potential savings and improved patient care that we believe are likely. With some significant exceptions discussed earlier in this preamble, mainly focused on anesthesiology or on medical governance received from physicians, we received overwhelming support for these proposals. All major non-physician stakeholder groups supported our reforms and the likely magnitude of savings.

Nursing Services Care Plan (§ 482.23)

The current hospital CoPs require that hospitals ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. In this final rule, we are allowing those hospitals that have interdisciplinary care plans (ICPs) to have their nursing care plans developed and kept current as part of the hospital's ICPs.

Based on our experience with hospitals, a nurse would develop and maintain the nursing care plan for each patient. The nurse would also be responsible for identifying the sections of each nursing care plan that needed to be integrated into the hospital's ICP and transferring that information into the ICP. Thus, allowing hospitals to include the nursing care plan in the ICP for each patient would save the nurse the time he or she is currently spending identifying and transferring information from the separate nursing care plan into the ICP and maintaining the separate nursing care plan. We believe that many hospitals have already developed methods for eliminating this time-wasting step, particularly those hospitals that have largely implemented an electronic health records system. Assuming that about 60 percent have done so, this reform would only affect

roughly 16 million patients (40 percent of 40 million admissions).

We estimate that allowing a hospital to use only the ICP would save the nurse an average of nine minutes or 0.15 hours and would affect 16,000,000 patients. Thus, this would result in a reduction of 2,400,000 burden hours valued at $45 per hour for a savings of $108,000,000. The comments we received by nursing groups and other expert reviewers strongly supported our policy change and these overall estimates, though without providing any empirical support for the precise savings we estimated.

Medical Record Services—Authentication and Standing Orders (§ 482.24)

In this final rule, we are revising the Medical Records CoP to eliminate the requirement for authentication of verbal orders within 48 hours if no State law specifying a timeframe exists. Since we believe that very few States have authentication timeframe requirements, we do not believe that the few States that may have such requirements would impact the potential savings we are estimating here. We also are making permanent the temporary provision (5-year sunset provision which expired in early 2012) that allows for orders to be authenticated by another practitioner who is responsible for the care of the patient and who, in accordance with hospital policy State law, is authorized to write orders.

We believe that this provision would result in a burden reduction. We would expect a registered nurse or compliance officer to be responsible for checking medical records and flagging orders needing authentication, particularly those verbal orders nearing the current 48-hr timeframe. Based on our experience with hospitals and feedback from stakeholders on this issue, we believe that hospitals will save one hour of a nurse's time every day for 365 burden hours for each hospital annually. For all 4,900 hospitals, this would result in a reduction of 1,788,500 burden hours, valued at $45 per hour for a savings of $80,482,500.

We are also adding new provisions to allow hospitals to use pre-printed and electronic standing orders, order sets, and protocols for patient orders if the hospital ensures that these orders: Have been reviewed and approved by the medical staff and nursing and pharmacy leadership; are consistent with nationally recognized guidelines; are reviewed periodically and regularly by medical staff and nursing and pharmacy leadership; and are dated, timed, and authenticated by a practitioner who is responsible for the care of the patient and who is authorized to write orders by hospital policy in accordance with State law. In addition, we proposed to allow for drugs and biologicals to be prepared and administered on the orders of other practitioners if they are acting in accordance with State law and scope of practice and the hospital has granted them the privileges to do so.

The use of standing orders, order sets, and protocols reduces a hospital's burden in several ways. Initially, it saves the physician or other practitioner the time it takes to write out the orders. It also saves the physician the time it would take to go back to the chart or call a nurse with a verbal order if the physician forgets a particular order. The nurses also save time when standing orders are used. The orders are more legible so there is less time interpreting and calling physicians for verification. Nurses also need to call physicians less frequently when there is a change in the patient's condition or they feel there needs to be a change in the care the patient is receiving. Patients also benefit from standing orders because there would be less delay in the delivery of needed care to a patient. Thus, we believe that expanding the use of standing orders would significantly reduce the hospital's burden.

Based on our experience with hospitals and on stakeholder feedback regarding the issue of standing orders, we estimate that these provisions would affect 13 million patients or roughly one-third of hospital admissions. We also estimate that using standing orders would result in a burden reduction of an average of 4 minutes or 0.07 hours for each of these patients. Thus, expanding the use of standing orders would result in a reduction of 700,000 burden hours valued at $124 per hour for a savings of $86,800,000. As discussed in the Information Collection section, comments overwhelmingly supported this reform and did not suggest specific changes in our estimates.

Outpatient Services (§ 482.54)

Allowing one or more individuals to be responsible for the supervision of outpatient services would permit large savings in this final rule. Under the existing CoP, only one person may direct outpatient services. Similar to our estimates for medical staff savings, what savings hospitals may realize would depend largely on their future decisions, and cannot be predicted with any precision. For purposes of estimation, we have developed an estimate that illustrates that potential. Based upon our experience with hospitals, we estimate that two-thirds of the hours eliminated would represent net savings, since existing directors obviously perform significant coordination functions that would have to be performed regardless of how the work is organized. To be more specific, potential savings are based on the following:

- Two-thirds of hospitals elected to redirect these overall director functions (3,267 hospitals);
- On average, each position represents 2,000 hours per year;
- Only two-thirds of the hours eliminated represented net savings; and
- Compensation averages about $70 an hour.

Based on these assumptions, this reform would produce $305 million annually in staff savings (3,267 hospitals × 2,000 hours × ⅔ × $70 per hour). A similar result would be obtained if four-fifths of hospitals redirected these functions, but the net hours saved were only a little more than half of the current hours. We received very few comments on this reform, but all of these supported the reform and agreed it would produce substantial savings.

Transplant Organ Recovery (§ 482.92)

We are removing the current blood typing requirement entirely. The elimination of this section removes transplant center burden by eliminating a requirement to review and compare blood type and other vital data before organ recovery takes place. The OPOs already perform this type of verification prior to organ recovery. In addition, since publication of the existing rule, the transplant community has repeatedly told CMS that the verification that we are deleting is burdensome and unnecessary.

Under the current requirements for this situation, the OPO performs a verification before organ recovery, the surgeon working for the transplant center performs a verification before organ recovery, and the transplant center surgeon performs another verification before the organ is transplanted. Under this finalized requirement, the OPO performs a verification before organ recovery and the transplant center surgeon performs a verification before the organ is transplanted. We are eliminating the verification that is conducted by the staff working on behalf of the transplant center that must occur prior to organ recovery. In addition, the responsibility for maintaining these records is very unclear, and has caused conflict between surgeons, transplant centers, and the hospitals where the organ recoveries are performed. Eliminating

the extra verification step removes this source of conflict and confusion.

Between July 1, 2009 and June 30, 2010, the United States saw 2,293 heart and 1,699 lung transplants. During the same time frame, there were also 16,679 transplants for kidneys, 6,301 for livers, and 371 for pancreases. (Scientific Registry of Transplant Recipients (SRTR) *http://srtr.org/csr/current/nats.aspx,* date last accessed 6/9/10). Surgeons working for their own transplant centers conduct most organ recoveries for heart and lung transplants. By contrast, in the case of kidneys, livers, and pancreases, these organs are typically recovered by surgeons who are on-call for an OPO and who are not also working for, or privileged at, the same transplant center where the organ is delivered. Based on our experience with transplant centers, we estimate that surgeons who are working for the transplant centers conduct 25 percent of kidney, liver and pancreas organ recoveries. It is in this small percentage of transplant cases, roughly 5,800, together with the total number of heart and lung transplants, where the requirement for an additional verification has resulted in overlapping and burdensome requirements. For the purpose of analysis, we have assumed that conducting the verification and filing the corresponding paperwork would take 8 minutes and that there are 9,972 transplant cases. We therefore conclude that removing the duplicative verification requirement will result in an annual savings of 1,305 burden hours valued at $124 per hour for a monetary savings of $161,820.

Several commenters pointed out that we would need to change our IG to surveyors to assure these savings. We agree, and will make the necessary changes.

Infection Control Log (§ 484.42)

We are eliminating a requirement for keeping a dedicated log of incidents related to infections and communicable diseases, and instead allowing hospitals flexibility in their approach to the tracking and surveillance of infections. We believe the changes we are finalizing would result in the more efficient use of time.

We believe that the current log requirement requires roughly 30 hours annually of a nurse's time per hospital (that is., an average of 600 to 900 log entries per year and 2–3 minutes per entry). Thus, for all 4,900 hospitals this change would result in a savings of 147,000 burden hours valued at $45 per hour for a savings of $6,615,000. Again, we received no comments suggesting that these savings could not be realized.

CAH Provision of Services (§ 485.635)

Our removal of the ''direct services'' requirement imposed on CAHs would eliminate the requirement that certain services be provided only by employees and not through contractual arrangements with entities such as community physicians, laboratories, or radiology services. Opportunities may be limited because CAHs are both small and overwhelmingly located in rural areas where there may not be realistic alternatives to direct hiring. We estimate that this could produce savings of approximately one tenth of one full-time equivalent staff person in payroll savings on average, at an average compensation cost of $66, for a total of about $16 million saved annually across all 1,200 CAHs. This is an area where our savings may well be underestimated, based on the tenor of the comments we received. We did not, however, obtain suggestions for specific changes.

5. Alternatives Considered

From within the entire body of CoPs, the most serious candidates for reform were those identified by stakeholders, by recent research, or by experts as unusually burdensome if not unchanged. This subset of the universe of standards is the focus of this final rule.

For each requirement that we have deleted or modified, there were a number of possible options, including making no change, making the change we proposed, and in some but not all cases making some in-between change. There was a final set of alternatives revolving around entirely different methods of achieving potential benefits, such as incentive payments through Medicare or other health plans to high-performing institutions, or publishing quality scores to make hospital strengths and weaknesses transparent to both the public at large and to practitioners. A number of such reforms are underway. Likewise, there are alternatives such as technical assistance through Quality Improvement Organizations (QIOs) funded by CMS, also underway under the latest QIO contracts.

Throughout the preamble to this final rule, we have identified ways to improve, avoid problems, or clarify the proposed reforms. Many of these improvements arose directly from public comments. While some of those changes are vital to realizing the reforms we proposed, most of the final rule changes required no substantial changes to our estimates of the potential reductions in regulatory burden.

6. Uncertainty

Our estimates of the effects of this regulation are subject to significant uncertainty. While CMS is confident that these reforms would provide flexibilities to hospitals that would yield cost savings, we are uncertain about the magnitude of these effects. In addition, as we previously explained, we do not believe that any eliminated requirement contributed in any consequential way to patient safety. Thus, we are confident that the final rule yields net benefits. In this analysis, we provided some illustrative estimates to suggest the potential savings these reforms could achieve under certain assumptions. We appreciate that those assumptions are simplified, and that actual results could be substantially higher or lower. We have no basis for estimating the range of uncertainty with any precision. Moreover, in the set of calculations for each reform one assumption might be too high and another too low, with these offsetting effects leading to a similar overall saving even though each component of the calculation could be substantially higher or lower. Therefore, no one set of range estimates could capture the many uncertainties involved. We plan to evaluate these reforms over time, and welcome independent external evaluations of their effects by professional societies, individual hospitals, hospital associations, academics, and others. We are particularly interested in evidence as to actual savings in time and effort realized as hospitals implement the increased flexibility provided by these reforms.

7. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), we have prepared an accounting statement. As previously explained, achieving the full scope of potential savings will depend on future decisions by hospitals, by State regulators, and others. Many other factors will influence long-term results. We believe, however, that likely savings and benefits will reach many billions of dollars. Our primary estimate of the net savings to hospitals from reductions in regulatory requirements that we can quantify at this time, offset by increases in other regulatory costs, are approximately $940 million a year.

TABLE 2—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS AND SAVINGS

[$ In millions]

Category	Primary estimate	Units		
		Year dollars	Discount rate	Period covered
Benefits	None			
Costs:				
Annualized Monetized reductions in Costs	−$940	2012	7%	2012–16
	−$940	2012	3%	2012–16
Transfers	None			

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), as modified by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), requires agencies to determine whether proposed or final rules would have a ''significant economic impact on a substantial number of small entities'' and, if so, to prepare a Regulatory Flexibility Analysis and to identify in the notice of proposed rulemaking or final rulemaking any regulatory options that could mitigate the impact of the proposed regulation on small businesses. For purposes of the RFA, small entities include businesses that are small as determined by size standards issued by the Small Business Administration (SBA), nonprofit organizations, and small governmental jurisdictions. Individuals and States are not included in the definition of a small entity. The SBA size threshold for ''small entity'' hospitals is $34.5 million or less in annual revenues. In addition, all non-profit hospitals are small entities under the RFA. About three-fifths of all hospitals (including CAHs) are non-profit and about one-third (many overlapping) have annual revenues below the SBA size threshold. Because the great majority qualifies as ''small entities,'' HHS policy for many years has been to treat all hospitals as small entities deserving protection under the RFA. Although the overall magnitude of the paperwork, staffing, and related cost reductions to hospitals and CAHs under this rule is economically significant, these savings are likely to be only about one percent of total hospital costs. Total national inpatient hospital spending is approximately nine hundred billion dollars a year, or an average of about $150 million per hospital, and our primary estimate of the net effect of these proposals on reducing hospital costs is only about $940 million annually (although potentially far higher). This is an average of slightly over $150,000 in savings on average for the 6,100 hospitals (including CAHs) that are regulated through the CoPs. Under HHS guidelines for Regulatory Flexibility Analysis, actions that do not negatively affect costs or revenues by about 3 to 5 percent a year are not economically significant. We believe that no hospitals of any size will be negatively affected. Accordingly, we have determined that this final rule would not have a significant economic impact on a substantial number of small entities, and that a Final Regulatory Flexibility Analysis is not required. Notwithstanding this conclusion, we believe that this RIA and the preamble as a whole meet the requirements of the RFA for such an analysis.

In addition, section 1102(b) of the Social Security 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 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. We do not believe a regulatory impact analysis is required here for the same reasons previously described and because, in addition, our proposals are particularly cost-reducing for the smallest hospitals, including especially CAHs (which in most cases have no more than 25 beds).

C. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates on State, local, or tribal governments in the aggregate, or on the private sector, require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently about $139 million. This final rule would eliminate or reform existing requirements and would allow hospitals and CAHs to achieve substantial savings through staffing reforms. Accordingly, no analysis under UMRA is required.

D. Federalism

Executive Order 13132 on Federalism establishes certain requirements that an agency must meet when it publishes 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. We have determined that this final rule would not significantly affect the rights, roles, or responsibilities of the States. This final rule would not impose substantial direct requirement costs on State or local governments, preempt State law, or otherwise implicate federalism. It does, however, facilitate the ability of States to reform their scope of practice laws without Federal requirements reducing the effectiveness of such reforms. We received several comments on the Federalism analysis in the proposed rule and respond as follows. The problem facing States considering reforms in scope of practice and other laws was that our previous rules would in many areas have rendered useless State reforms, since we dictated stringent limits on non-physician roles. By removing these unnecessary limits, we are enabling States to consider such reforms without Federal constraints that, while not legally preemptive, in practical effect would have nullified potential State reforms. We believe that some States are therefore likely to legislate reforms that would take advantage of this increased flexibility to reduce health care costs by allowing non-physician practitioners to utilize the full scope of their training and expertise. We support this increased flexibility for States to make reforms that they determine are professionally appropriate and reduce health care costs while protecting or improving patient care.

Regulations Text

List of Subjects

42 CFR Part 482

Grant programs—Health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs—Health, Health facilities, Medicaid, Medicare, 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 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 1. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

Subpart B—Administration

■ 2. Section 482.12 is amended by revising the introductory text to read as follows:

§ 482.12 Condition of participation: Governing body.

There must be an effective governing body that is legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body. The governing body (or the persons legally responsible for the conduct of the hospital and carrying out the functions specified in this part that pertain to the governing body) must include a member, or members, of the hospital's medical staff.

* * * * *

■ 3. Section 482.13 is amended by —

■ a. Revising paragraphs (g)(1) through (3).

■ b. Adding paragraph (g)(4).

The revisions and addition read as follows:

§ 482.13 Condition of participation: Patient's rights.

* * * * *

(g) * * *

(1) With the exception of deaths described under paragraph (g)(2) of this section, the hospital must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death:

(i) Each death that occurs while a patient is in restraint or seclusion.

(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. ''Reasonable to assume'' in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

(2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must record in an internal log or other system, the following information:

(i) Any death that occurs while a patient is in such restraints.

(ii) Any death that occurs within 24 hours after a patient has been removed from such restraints.

(3) The staff must document in the patient's medical record the date and time the death was:

(i) Reported to CMS for deaths described in paragraph (g)(1) of this section; or

(ii) Recorded in the internal log or other system for deaths described in paragraph (g)(2) of this section.

(4) For deaths described in paragraph (g)(2) of this section, entries into the internal log or other system must be documented as follows:

(i) Each entry must be made not later than seven days after the date of death of the patient.

(ii) Each entry must document the patient's name, date of birth, date of death, name of attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c), medical record number, and primary diagnosis(es).

(iii) The information must be made available in either written or electronic form to CMS immediately upon request.

* * * * *

Subpart C—Basic Hospital Functions

■ 4. Section 482.22 is amended by revising paragraphs (a) introductory text, (a)(2), and (b)(3) to read as follows:

§ 482.22 Condition of participation: Medical staff.

* * * * *

(a) *Standard: Eligibility and process for appointment to medical staff.* The medical staff must include doctors of medicine or osteopathy. In accordance with State law, including scope-of-practice laws, the medical staff may also include other categories of non-physician practitioners determined as eligible for appointment by the governing body.

* * * * *

(2) The medical staff must examine the credentials of all eligible candidates for medical staff membership and make recommendations to the governing body on the appointment of these candidates in accordance with State law, including scope-of-practice laws, and the medical staff bylaws, rules, and regulations. A candidate who has been recommended by the medical staff and who has been appointed by the governing body is subject to all medical staff bylaws, rules, and regulations, in addition to the requirements contained in this section.

* * * * *

(b) * * *

(3) The responsibility for organization and conduct of the medical staff must be assigned only to one of the following:

(i) An individual doctor of medicine or osteopathy.

(ii) A doctor of dental surgery or dental medicine, when permitted by State law of the State in which the hospital is located.

(iii) A doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located.

* * * * *

■ 5. Section 482.23 is amended by revising paragraphs (b)(4) and (c) to read as follows:

§ 482.23 Condition of participation: Nursing services.

* * * * *

(b) * * *

(4) The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. The nursing care plan may be part of an interdisciplinary care plan.

* * * * *

(c) *Standard: Preparation and administration of drugs.* (1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under § 482.12(c), and accepted standards of practice.

(i) Drugs and biologicals may be prepared and administered on the

orders of other practitioners not specified under § 482.12(c) only if such practitioners are acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

(ii) Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of § 482.24(c)(3).

(2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

(3) With the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy, and who is responsible for the care of the patient as specified under § 482.12(c).

(i) If verbal orders are used, they are to be used infrequently.

(ii) When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and State law.

(iii) Orders for drugs and biologicals may be documented and signed by other practitioners not specified under § 482.12(c) only if such practitioners are acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

(4) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures.

(5) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

(6) The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures.

(i) If the hospital allows a patient to self-administer specific hospital-issued medications, then the hospital must have policies and procedures in place to:

(A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration.

(B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s).

(C) Instruct the patient (or the patient's caregiver/support person where appropriate) in the safe and accurate administration of the specified medication(s).

(D) Address the security of the medication(s) for each patient.

(E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.

(ii) If the hospital allows a patient to self-administer his or her own specific medications brought into the hospital, then the hospital must have policies and procedures in place to:

(A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration of medications the patient brought into the hospital.

(B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s), and also determine if the patient (or the patient's caregiver/support person where appropriate) needs instruction in the safe and accurate administration of the specified medication(s).

(C) Identify the specified medication(s) and visually evaluate the medication(s) for integrity.

(D) Address the security of the medication(s) for each patient.

(E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.

■ 6. Section 482.24 is amended by—

■ a. Removing paragraphs (c)(1)(i) through (iii).

■ b. Redesignating (c)(2) as (c)(4).

■ c. Adding a new paragraphs (c)(2) and (3).

The additions read as follows:

§ 482.24 Condition of participation: Medical record services.

* * * * *

(c) * * *

(2) All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

(3) Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:

(i) Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership;

(ii) Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;

(iii) Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and

(iv) Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or by another practitioner responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

* * * * *

■ 7. In § 482.25, paragraph (b)(6) is revised to read as follows:

§ 482.25 Condition of participation: Pharmaceutical services.

* * * * *

(b) * * *

(6) Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital's quality assessment and performance improvement program.

* * * * *

■ 8. Section 482.42 is amended by revising paragraphs (a) introductory text and (b)(1) to read as follows:

§ 482.42 Condition of participation: Infection control.

* * * * *

(a) *Standard: Organization and policies.* A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases. The infection control officer or officers must develop a system for identifying,

reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

* * * * *

(b) * * *

(1) Ensure that the hospital-wide quality assessment and performance improvement (QAPI) program and training programs address problems identified by the infection control officer or officers; and

* * * * *

Subpart D—Optional Hospital Services

■ 9. Section 482.54 is amended by revising paragraph (b) to read as follows:

§ 482.54 Condition of participation: Outpatient services.

* * * * *

(b) *Standard: Personnel.* The hospital must—

(1) Assign one or more individuals to be responsible for outpatient services.

(2) Have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, based on the scope and complexity of outpatient services.

Subpart E—Requirements for Specialty Hospitals.

§ 482.92 [Amended]

■ 10. Section 482.92 is amended by—

■ a. Removing paragraph (a).

■ b. Redesignating paragraphs (b) and (c) as (a) and (b) respectively.

PART 485—CONDITIONS OF PARTICIPATION SPECIALIZED PROVIDERS

■ 11. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

§ 485.602 [Removed]

■ 12. Section 485.602 is removed.

■ 13. In § 485.604, paragraph (a) is revised to read as follows:

§ 485.604 Personnel qualifications.

* * * * *

(a) *Clinical nurse specialist.* A clinical nurse specialist must be a person who—

(1) Is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed in accordance with State nurse licensing laws and regulations; and

(2) Holds a master's or doctoral level degree in a defined clinical area of nursing from an accredited educational institution.

* * * * *

■ 14. In § 485.623, paragraph (a) is revised to read as follows:

§ 485.623 Condition of participation: Physical plant and environment.

(a) *Standard: Construction.* The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of services.

* * * * *

■ 15. In § 485.635, paragraphs (a)(3)(i) and (b) are revised to read as follows:

§ 485.635 Condition of participation: Provision of services.

(a) * * *

(3) * * *

(i) A description of the services the CAH furnishes, including those furnished through agreement or arrangement.

* * * * *

(b) *Standard: Patient services.* (1) *General:* The CAH provides those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These CAH services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

(2) *Laboratory services.* The CAH provides basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include the following:

(i) Chemical examination of urine by stick or tablet method or both (including urine ketones).

(ii) Hemoglobin or hematocrit.

(iii) Blood glucose.

(iv) Examination of stool specimens for occult blood.

(v) Pregnancy tests.

(vi) Primary culturing for transmittal to a certified laboratory.

(3) *Radiology services.* Radiology services furnished by the CAH are provided by personnel qualified under State law, and do not expose CAH patients or personnel to radiation hazards.

(4) *Emergency procedures.* In accordance with requirements of § 485.618, the CAH provides medical services as a first response to common life-threatening injuries and acute illness.

* * * * *

■ 16. Section 485.639 is amended by revising the introductory text to read as follows:

§ 485.639 Condition of participation: Surgical services.

If a CAH provides surgical services, surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body, or responsible individual, of the CAH in accordance with the designation requirements under paragraph (a) of this section.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: March 19, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: April 2, 2012.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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