

use shall be part of the batch record. The persons performing and double-checking the cleaning and maintenance (or, if the cleaning and maintenance is performed using automated equipment under § 211.68, only the person verifying the cleaning and maintenance done by the automated equipment) shall date and sign or initial the log indicating that the work was performed. Entries in the log shall be in chronological order.

■ 17. Section 211.188 is amended by revising paragraph (b)(11) to read as follows:

**§ 211.188 Batch production and control records.**

\* \* \* \* \*

(b) \* \* \*  
 (11) Identification of the persons performing and directly supervising or checking each significant step in the operation, or if a significant step in the operation is performed by automated equipment under § 211.68, the identification of the person checking the significant step performed by the automated equipment.

\* \* \* \* \*

Dated: November 26, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7-23294 Filed 12-3-07; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF VETERANS AFFAIRS**

**38 CFR Part 17**

**RIN 2900-AM35**

**Reasonable Charges for Medical Care or Services**

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Final rule.

**SUMMARY:** This final rule amends the Department of Veterans Affairs (VA) medical regulations concerning “reasonable charges” for medical care or services provided or furnished by VA to certain veterans for nonservice-connected disabilities. It changes the process for determining interim billing charges when a new Diagnosis Related Group (DRG) code or Current Procedural Terminology/Healthcare Common Procedure Coding System (CPT/HCPCS) code identifier is assigned to a particular type or item of medical care or service and VA has not yet established a charge for the new identifier. This process is designed to provide interim billing charges that are very close to what the new billing

charges would be when the charges for the new identifiers are established in accordance with the regulations. This final rule also changes the regulations by removing all of the provisions for discounts of billed charges. This will eliminate or reduce duplicate discounting and thereby prevent unintended underpayments to the government.

**DATES:** *Effective Date:* January 3, 2008.

**FOR FURTHER INFORMATION CONTACT:** Romona Greene, Manager of Rates and Charges, VHA Chief Business Office (168), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 254-0361.

**SUPPLEMENTARY INFORMATION:** In a document published in the **Federal Register** on February 13, 2007 (72 FR 6696), VA proposed to amend VA’s medical regulations that were established under the authority of 38 U.S.C. 1729 and that are set forth in 38 CFR 17.101 (referred to below as “the regulations”). The regulations establish methodologies for determining reasonable charges for medical care or services provided or furnished by VA to certain veterans. VA proposed to make the changes described in the **SUMMARY** portion of this document.

VA provided a 30-day comment period that ended March 15, 2007. Two comments were received. One comment did not directly express agreement or disagreement with the proposed rule, but provided information about Medicare requirements. We reviewed that information and determined that the proposed rule is consistent with those Medicare provisions. Accordingly, we are making no change from the proposed rule based on that comment. We discuss below the second comment, and include background concerning provisions of the proposed rule related to that comment.

Under the provisions of 38 U.S.C. 1729, VA has the right to recover or collect reasonable charges for such medical care and services from a third party to the extent that the veteran or a provider of the care or services would be eligible to receive payment for:

1. A nonservice-connected disability for which the veteran is entitled to care (or the payment of expenses of care) under a health plan contract;

2. A nonservice-connected disability incurred incident to the veteran’s employment and covered under a worker’s compensation law or plan that provides reimbursement or indemnification for such care and services; or

3. A nonservice-connected disability incurred as a result of a motor vehicle accident in a State that requires automobile accident reparations (no-fault) insurance.

However, consistent with the statutory authority in 38 U.S.C. 1729(c)(2)(B), a third-party payer liable for such medical care and services under a health plan contract has the option of paying, to the extent of its coverage, either the billed charges or the amount the third-party payer demonstrates it would pay for care or services furnished by providers other than entities of the United States for the same care or services in the same geographic area.

Except for charges for prescription drugs, the regulations were promulgated to describe methodologies for establishing VA charges that replicate, insofar as possible, the 80th percentile of community charges (see the preamble to VA’s proposed rule “Reasonable Charges for Medical Care or Services; 2003 Methodology Changes” published in the **Federal Register** at 68 FR 56876 (Oct. 2, 2003)). VA’s methodologies for determining reasonable charges for prescription drugs are based on VA costs and are described in 38 CFR 17.102.

Prior to the effective date of this final rule, the regulations included provisions for certain discounts to be applied to billed charges. The discounts were intended to reflect industry standards. VA proposed to eliminate discounts for VA billed charges to avoid unintended duplicate discounting. This was necessary because after VA applied discounts to the billed charges, virtually all third party-payers applied the same discounts a second time (discounts are included in industry software), thereby reducing the billed charges below what was intended by the regulations. VA accordingly proposed to make a number of changes to the regulations to eliminate VA discounts, including changing the regulations at § 17.101(f)(5)(ii) to increase the charges for the professional services of the following providers to 100 percent of the amount that would be charged if the care had been provided by a physician:

- Nurse practitioner,
- Clinical nurse specialist,
- Physician Assistant,
- Clinical psychologist,
- Clinical social worker,
- Dietitian, and
- Clinical pharmacist.

The second comment noted that Public Law 109-461 recently added marriage and family therapists to the groups eligible to provide care under the VA healthcare system and requested

that this group be added accordingly to the list in § 17.101(f)(5)(ii). The second comment otherwise fully supported the proposed rule.

Section 201 of Public Law 109-461 amended 38 U.S.C. 7401 and 7402 to add provisions under which qualified marriage and family therapists are identified as eligible to provide care under the VA healthcare system. Section 201 also amended 38 U.S.C. 7401 and 7402 to add provisions under which qualified licensed professional mental health counselors are similarly identified as eligible to provide care under the VA healthcare system. VA has concluded that these statutory provisions make it appropriate to make changes from the proposed rule in the final rule to include provisions concerning both categories: Providers that are marriage and family therapists, and providers that are licensed professional mental health counselors. Third party payers apply discounts from the physician rate for marriage and family therapists and for licensed professional mental health counselors, as third party payers similarly do for the other providers included in the lists in current and proposed § 17.101(f)(5)(ii). Accordingly, after considering the second comment, we are making a change from the proposed rule in the final rule by adding marriage and family therapists and licensed professional mental health counselors to the list of providers in § 17.101(f)(5)(ii). Charges for professional services of the providers included in that list will be 100 percent of the amount that would be charged if the care had been provided by a physician.

This final rule is making other changes from the proposed rule that are nonsubstantive. In the § 17.101(g) introductory paragraph, VA proposed to amend a sentence by removing “50 percent” and replacing it with “100 percent”. That sentence says in the current regulations that certain charges “will be 50 percent of the charges otherwise determined as set forth in this paragraph.” This final rule further amends the sentence by removing “otherwise” since that term would no longer be needed.

This final rule also makes a nonsubstantive change from the proposed rule’s provisions for the authority citation for 38 CFR part 17, so that the final rule will, as intended by the proposed rule, reflect the current language in the part 17 authority citation.

In addition, the final rule makes nonsubstantive changes from the proposed rule for purposes of clarity or grammar. Other than nonsubstantive

changes in capitalization or punctuation, those changes from the proposed rule are in § 17.101(a)(8)(i) to refer to “billing charge” rather than “billable charge”, in § 17.101(a)(8)(iii) to refer to “VA’s billing charge” rather than “VA’s charge”, in § 17.101(a)(8)(vii) to refer to “the interim charge” to use the same phrase as in the similar context in paragraphs (a)(8)(iv) and (a)(8)(v) of that section, and in § 17.101(a)(8)(vii) to add for clarity “under this section”, which is used in the current regulations in the analogous provisions of § 17.101(a)(8)(v) of the regulations but was not in the proposed rule.

Based on the rationale set forth in the proposed rule and in this document, VA is adopting the provisions of the proposed rule as a final rule with the changes discussed above.

#### **Unfunded Mandates**

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any given year. This rule would have no such effect on State, local, and tribal governments, or on the private sector.

#### **Paperwork Reduction Act**

This document contains no collections of information under the Paperwork Reduction Act (44 U.S.C. 3501-3521).

#### **Executive Order 12866**

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Order classifies a rule as a significant regulatory action requiring review by the Office of Management and Budget if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of \$100 million or more, creating a serious inconsistency or interfering with an action of another agency, materially altering the budgetary impact of entitlements or the rights of entitlement recipients, or raising novel legal or policy issues. VA has examined the economic, legal, and policy implications of this rule and has concluded that it is

a significant regulatory action under Executive Order 12866.

#### **Regulatory Flexibility Act**

The Secretary hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. This rule would affect mainly large insurance companies. The rule might have an insignificant impact on a few small entities that do an inconsequential amount of their business with VA. Accordingly, pursuant to 5 U.S.C. 605(b), this rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

#### **Catalog of Federal Domestic Assistance**

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.005, Grants to States for Construction of State Home Facilities; 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.016, Veterans State Hospital Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; and 64.022, Veterans Home Based Primary Care.

#### **List of Subjects in 38 CFR Part 17**

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Approved: August 27, 2007.

**Gordon H. Mansfield,**

*Deputy Secretary of Veterans Affairs.*

■ For the reasons set out in the preamble, VA amends 38 CFR part 17 as set forth below:

#### **PART 17—MEDICAL**

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 38 U.S.C. 501, 1721, and as stated in specific sections.

■ 2. Amend § 17.101 by:

■ a. In paragraph (g) introductory text, removing "50 percent of the charges otherwise" and adding, in its place, "100 percent of the charges".

■ b. Revising paragraphs (a)(8), (e)(5), (f)(4), and (f)(5)(ii).

The revisions read as follows:

§ 17.101 Collection or recovery by VA for medical care or services provided or furnished to a veteran for a nonservice-connected disability.

(a) \* \* \*

(8) Charges when a new DRG or CPT/HCPCS code identifier does not have an established charge. When VA does not have an established charge for a new DRG or CPT/HCPCS code to be used in determining a billing charge under the applicable methodology in this section, then VA will establish an interim billing charge or establish an interim charge to be used for determining a billing charge under the applicable methodology in paragraphs (a)(8)(i) through (a)(8)(viii) of this section.

(i) If a new DRG or CPT/HCPCS code identifier replaces a DRG or CPT/HCPCS code identifier, the most recently established charge for the identifier being replaced will continue to be used for determining a billing charge under paragraphs (b), (e), (f), (g), (h), (i), (k), or (l) of this section until such time as VA establishes a charge for the new identifier.

(ii) If medical care or service is provided or furnished at VA expense by a non-VA provider and a charge cannot be established under paragraph (a)(8)(i) of this section, then VA's billing charge for such care or service will be the amount VA paid to the non-VA provider without additional calculations under this section.

(iii) If a new CPT/HCPCS code has been established for a prosthetic device or durable medical equipment subject to paragraph (l) of this section and a charge cannot be established under paragraphs (a)(8)(i) or (ii) of this section, VA's billing charge for such prosthetic device or durable medical equipment will be 1 and 1/2 times VA's average actual cost without additional calculations under this section.

(iv) If a new medical identifier DRG code has been assigned to a particular type of medical care or service and a charge cannot be established under paragraphs (a)(8)(i) through (iii) of this section, then until such time as VA establishes a charge for the new medical identifier DRG code, the interim charge for use in paragraph (b) of this section will be the average charge of all medical

DRG codes that are within plus or minus 10 of the numerical relative weight assigned to the new medical identifier DRG code.

(v) If a new surgical identifier DRG code has been assigned to a particular type of medical care or service and a charge cannot be established under paragraphs (a)(8)(i) through (iv) of this section, then until such time as VA establishes a charge for the new surgical identifier DRG code, the interim charge for use in paragraph (b) of this section will be the average charge of all surgical DRG codes that are within plus or minus 10 of the numerical relative weight assigned to the new surgical identifier DRG code.

(vi) If a new identifier CPT/HCPCS code is assigned to a particular type or item of medical care or service and a charge cannot be established under paragraphs (a)(8)(i) through (v) of this section, then until such time as VA establishes a charge for the new identifier for use in paragraphs (e), (f), (g), (h), (i), (k), or (l) of this section, VA's billing charge will be the Medicare allowable charge multiplied by 1 and 1/2, without additional calculations under this section.

(vii) If a new identifier CPT/HCPCS code is assigned to a particular type or item of medical care or service and a charge cannot be established under paragraphs (a)(8)(i) through (vi) of this section, then until such time as VA establishes a charge for the new identifier, the interim charge for use in paragraphs (e), (f), (g), (h), (i), (k), or (l) of this section will be the charge for the CPT/HCPCS code that is closest in characteristics to the new CPT/HCPCS code.

(viii) If a charge cannot be established under paragraphs (a)(8)(i) through (a)(8)(vii) of this section, then VA will not charge under this section for the care or service.

\* \* \* \* \*

(e) \* \* \*

(5) Multiple surgical procedures. When multiple surgical procedures are performed during the same outpatient encounter by a provider or provider team as indicated by multiple surgical CPT/HCPCS procedure codes, then each CPT/HCPCS procedure code will be billed at 100 percent of the charges established under this section.

(f) \* \* \*

(4) Charge adjustment factors for specified CPT/HCPCS code modifiers. Surcharges are calculated in the following manner: From the Part B component of the Medicare Standard Analytical File 5 percent Sample, the ratio of weighted average billed charges

for CPT/HCPCS codes with the specified modifier to the weighted average billed charge for CPT/HCPCS codes with no charge modifier is calculated, using the frequency of procedure codes with the modifier as weights in both weighted average calculations. The resulting ratios constitute the surcharge factors for specified charge-significant CPT/HCPCS code modifiers.

(5) \* \* \*

(ii) Charges for professional services. Charges for the professional services of the following providers will be 100 percent of the amount that would be charged if the care had been provided by a physician:

- (A) Nurse practitioner.
(B) Clinical nurse specialist.
(C) Physician Assistant.
(D) Clinical psychologist.
(E) Clinical social worker.
(F) Dietitian.
(G) Clinical pharmacist.
(H) Marriage and family therapist.
(I) Licensed professional mental health counselor.

\* \* \* \* \*

[FR Doc. E7-23505 Filed 12-3-07; 8:45 am]

BILLING CODE 8320-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R07-OAR-2007-1055; FRL-8502-2]

Approval and Promulgation of Implementation Plans; State of Missouri; General Conformity

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve a revision to the Missouri State Implementation Plan (SIP) to amend the General Conformity Rule to include de minimis emission levels for Particulate Matter 2.5 (PM2.5). This update ensures consistency with the Federal General Conformity Rule.

DATES: This direct final rule will be effective February 4, 2008, without further notice, unless EPA receives adverse comment by January 3, 2008. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the Federal Register informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R07-OAR-2007-1055, by one of the following methods: