31 CFR Part 363

Bonds, Electronic funds transfer, Federal Reserve System, Government securities, Securities.

■ Accordingly, for the reasons set out in the preamble, 31 CFR Chapter II, Subchapter B, is amended as follows:

PART 357—REGULATIONS GOVERNING BOOK–ENTRY TREASURY BONDS, NOTES AND BILLS HELD IN TREASURY/RESERVE AUTOMATED DEBT ENTRY SYSTEM (TRADES) AND LEGACY TREASURY DIRECT

■ 1. The authority citation for part 357 continues to read as follows:

Authority: 31 U.S.C. chapter 31; 5 U.S.C. 301; 12 U.S.C. 391.

■ 2. Revise the heading for Part 357 to read as set forth above.

■ 3. Amend § 357.22 by removing paragraph (b) and redesignating paragraphs (c), (d), (e), and (f) as paragraphs (b), (c), (d), and (e).

PART 363—REGULATIONS GOVERNING SECURITIES HELD IN TREASURYDIRECT

■ 4. The authority citation for part 363 continues to read as follows:

Authority: 5 U.S.C. 301; 12 U.S.C. 391; 31 U.S.C. 3102, *et seq.;* 31 U.S.C. 3121, *et seq.*

§ 363.6 [Amended]

■ 5. Remove the definition of "Sell Direct" from § 363.6.

■ 6. Amend § 363.10 by adding paragraph (c) to read as follows:

§ 363.10 What is a TreasuryDirect account?

* * * * *

(c) *Closing an account.* If a TreasuryDirect primary account and all associated linked accounts have had no holdings and no activity for a period of two years, we reserve the right to close the account, along with all linked accounts.

§ 362 [Amended]

■ 7. Amend § 363.22 by removing the phrase "including a transfer for a Sell Direct transaction," from the second sentence in paragraph (a)(3)(ii).

§ 363.27 [Amended]

■ 8. Amend § 363.27 by removing the phrase ", and may request a Sell Direct transaction" from the second sentence in paragraph (e)(4).

§ 363.209 [Removed and reserved]

■ 9. Remove and reserve § 363.209.

§ 363.210 [Amended]

■ 10. Amend § 363.210 by removing the phrase "initiate a SellDirect transaction," from the second sentence and removing the fourth and fifth sentences.

Richard L. Gregg,

Fiscal Assistant Secretary.

[FR Doc. 2010–31489 Filed 12–16–10; 8:45 am]

BILLING CODE 4810–39–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AN37

Payment for Inpatient and Outpatient Health Care Professional Services at Non-Departmental Facilities and Other Medical Charges Associated With Non-VA Outpatient Care

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document affirms as final, with changes, a proposed rule that updates the Department of Veterans Affairs (VA) medical regulations concerning the payment methodology used to calculate VA payments for inpatient and outpatient health care professional services and other medical services associated with non-VA outpatient care. The rule has been designed to ensure that it will not have adverse effects on access to care.

DATES: This final rule is effective February 15, 2011.

FOR FURTHER INFORMATION CONTACT: Holley Niethammer, Supervisory Policy Specialist, National Fee Program Office, Department of Veterans Affairs, 3773 Cherry Creek North Dr., Suite 450, Denver, CO 80209, telephone (303) 370–5062. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Under 38 U.S.C. 1703(a), "[w]hen [VA] facilities are not capable of furnishing economical hospital care or medical services because of geographical inaccessibility or are not capable of furnishing the care or services required, the Secretary, as authorized in [38 U.S.C. 1710], may contract with non-[VA] facilities in order to furnish" certain hospital care and medical services to veterans who qualify under 38 U.S.C. 1703. VA implemented this authority in 38 CFR 17.52. Also, under 38 U.S.C. 1728, VA may authorize payment for emergency care in a non-VA facility in limited situations, primarily where the care is needed for the treatment of a service-connected disability or related condition. Under that authority, as implemented in 38 CFR 17.120, VA reimburses either the veteran who made payments for hospital care or medical services, the person or organization making such expenditure on behalf of such veteran, or the hospital or other health facility furnishing the care or services if such care or services were provided in a medical emergency and VA or other Federal facilities were not feasibly available, and an attempt to use them beforehand would not have been reasonable.

Payment methodology for health care professional services associated with outpatient and inpatient care that are payable under either 38 U.S.C. 1703 or 1728 is currently set forth in 38 CFR 17.56.

Current § 17.56(a) adopted the Medicare Participating Physician Fee Schedule for the payment of professional services. For services not covered by the Medicare Participating Physician Fee Schedule, VA pays the lesser of the actual amount billed or the amount calculated using the 75th percentile methodology set forth in current § 17.56(c) (or the usual and customary rate if there are fewer than 8 treatment occurrences for a procedure during the previous fiscal year). We cannot predict whether there will be 8 treatment occurrences during an upcoming fiscal year, or the precise charges of such treatment occurrences, because these depend upon the billing practices of the non-VA facilities involved. In the majority of these cases, the non-VA facilities' charges are far greater than the allowable Medicare charges for the same treatment. As a result, VA's expenditures can be unpredictable and, in some cases, can greatly exceed the costs VA would incur using the Medicare payment systems or fee schedules.

In a proposed rule published on February 18, 2010 (75 FR 7218), we proposed to amend § 17.56 to apply Medicare payment methodologies to all non-VA inpatient and outpatient health care professional services and other medical charges associated with non-VA outpatient care. We explained that such charges would include ancillary and facility costs such as those that are reimbursed using the following Medicare payment systems or fee schedules: Ambulatory Surgical Center Payment, Clinical Laboratory Fee Schedule, Home Health Prospective Payment System (PPS), Hospice, Hospital Outpatient PPS, and End Stage Renal Disease (ESRD) composite rate payment method (NOTE: Beginning January 1, 2011, Medicare will pay for

ESRD services based on the prospective bundled payment system, not the composite rate. We have revised this final rule to correctly utilize the prospective bundled payment system). We also proposed to revise the regulation to clarify how payments will be computed for inpatient and outpatient health care professional services at non-VA facilities and other medical charges associated with non-VA outpatient care. We concluded that using the Medicare payment systems and fee schedules will clearly help VA contain costs.

We received 18 comments on the proposed rule. All of the comments oppose at least one portion of the proposed rule. The proposed regulation governs multiple health service areas including but not limited to outpatient hospitals, ambulatory surgery centers, home health, ESRD, and laboratory services. The majority of comments concerned exclusively dialysis, thus VA's responses to the comments largely address only dialysis. The subject matter of most of the comments can be grouped into several categories, and we have organized our discussion of the comments accordingly.

We received no comments regarding the correction of the typographical error in 38 CFR 17.52(a). Prior versions of this regulation (codified at 38 CFR 17.50b(a)) included cross-references to 38 CFR 17.50c through f. Sections 17.50c, 17.50d and 17.50f have subsequently been recodified as 38 CFR 17.53, 17.54 and 17.55, respectively. 61 FR 21964 (1996). Additionally, since the most recent revision to this regulation, § 17.56 was added to the regulatory sequence. Therefore, we remove the reference in § 17.52(a) to "provisions of § 17.53 through f" and replace it with "provisions of §§ 17.53, 17.54, 17.55 and 17.56."

Challenges to VA's Legal Authority To Promulgate This Rule

Several commenters argued that VA lacks authority to establish by regulation rates to serve as default payment amounts in the absence of a negotiated payment amount, or in the context of individual authorizations for care. We disagree, but make clarifying changes to the regulation based on the comments. We will discuss these changes in reference to the comments before addressing our authority, because the clarifications themselves answer some of the comments.

Commenters expressed confusion between the preamble and the rule text regarding whether VA will enter into negotiated agreements if the agreed-upon rates are greater than the Medicare rate. In addition, commenters asked whether VA would be obligated to pay the negotiated amount in all contexts. We have clarified the regulatory text based on these comments. Depending upon agency need or prevailing market conditions, VA may negotiate specific rates with non-VA providers. If and when such contracts are awarded, VA will pay the negotiated contract rate for services within the contract's scope and terms. This negotiated rate could be greater than the Medicare rate.

In addition, nothing in the final rule authorizes VA to breach any contracts, including contracts which contain a negotiated rate. Some commenters expressed such a concern, as well as a concern that the rule would negate the payment terms of existing multi-Veterans Integrate Service Network (VISN) contracts or contracts negotiated pursuant to the Federal Acquisition Regulation (FAR) and the VA Acquisition Regulation (VAAR) for individual VISNs, and thus the rule represents a breach of contract and an unconstitutional taking under *United States* v. *Winstar Corp.,* 518 U.S. 839 (1996). Again, no such alteration to existing VISN or multi-VISN contracts would take place upon promulgation of this regulation. As the clarified hierarchy in the final rule more clearly establishes, contracts entered into pursuant to specific negotiation have precedence over the default rates, including the Medicare rate.

Finally, commenters indicated that the rule was unclear when it attempted to distinguish between a FAR contract and a VAAR contract. We agree that the proposed regulation text was confusing in this respect, and that this confusion may also have contributed to commenters' questions about the continuing authority to specifically negotiate rates with non-VA providers. We have removed the references to the FAR and VAAR because of this confusion. Nevertheless, as discussed below, the FAR and VAAR continue to be relevant to our authority to negotiate specific rates with specific providers, which we will pay under § 17.56(a)(1). We reassure the commenters that this regulation would not override or cancel out any contracts in existence upon promulgation of this final rule. Therefore, no breach of contract or constitutional/unconstitutional taking would occur. The modified regulatory language addresses the comments that expressed confusion about what payment mechanism VA will apply under a given circumstance.

We now address the specific challenges to VA's authority. Several commenters stated that VA does not have specific authority from Congress under 38 U.S.C. 1703 to promulgate this regulation, and therefore VA cannot set reimbursement rates or price controls. We disagree, and do not make any changes to the regulation based on this comment. Section 1703 gives VA the authority to contract with non-VA facilities to provide hospital care and medical services. This contracting authority is not limited to contracts which contain negotiated prices. For example, 38 CFR 17.52, which implements the authority granted by section 1703, allows for individual authorizations when demand is only for infrequent use. As discussed in more detail below, individual authorizations are essentially a price offer to the non-VA provider, who then accepts that offer by performing services for the VA patient. Thus, VA has always interpreted the contracting authority granted in section 1703 to include forms of contracts other than contracts containing negotiated prices. The commenters incorrectly assume that VA must have specific authority in 38 U.S.C. 1703 to include reimbursement rates in a regulation. However, VA has broad authority to issue regulations that are "necessary or appropriate to carry out the laws administered by the Department and are consistent with those laws." 38 U.S.C. 501(a).

Other commenters added that the FAR, VAAR, Competition in Contracting Act, Public Law 98–369, section 2701, and other Federal procurement laws and policies apply to all VA acquisitions made with appropriated funds unless explicitly exempted under 38 U.S.C. 8153, and stated that none of these provisions allow VA to set limitations on cost and require that VA negotiate contract prices. We disagree—none of these general contracting laws prohibits the contracting or payment provisions in the final rule. VA is authorized by the FAR, VAAR, and other Federal procurement laws and policies to enter into contracts to provide care to veterans through private providers. As noted above, our authority to enter contracts for this purpose is in fact specifically stated in 38 U.S.C. 1703 and 1728. These authorities—FAR, VAAR, and 38 U.S.C. 1703 and 1728—have long been the source of our authority to provide individual authorizations for care under 38 CFR 17.52. Moreover, these authorities do not prohibit VA's implementation of the specific contracting authority authorized in section 1703. Indeed, if these broader contracting laws prohibited the contracting arrangements described in the proposed rule, our arrangements

prior to the proposed revisions to § 17.56 would have been void; yet, the comments made no such assertion.

Thus, we have long-standing authority to engage in contracts and individual authorizations with non-VA providers. Inherent in VA's authority to enter into these contracts is our authority to set rate terms and conditions for those contracts. Some of these are specifically negotiated. Others, however, are governed by the specific amount-calculation mechanisms established in current § 17.56. Our proposed rule merely revised those calculation mechanisms, and made them applicable to a broader group of non-VA providers.

When VA offers to send a patient to a non-VA provider under the authority of § 17.56, and the non-VA provider accepts the patient and provides the service, a contract has been formed. In practice, these contract actions are ordered utilizing (1) VA Form 10–7078, Authorization and Invoice for Medical and Hospital Services, (2) VA Form 10–7079, Request for Outpatient Medical Services, or (3) VA Form 10–2570d, Dental Record Authorization and Invoice for Outpatient Service. The final rule merely indicates that the rate of payment for these contracts must conform to the regulation.

Under its acquisition protest authority, the Government Accountability Office (GAO) has found that similar pricing and contract arrangements were not unduly restrictive of competition. In a request for proposal (RFP), VA stated that the Medicare Fee Schedule rate in effect at the time and location of service would apply to prosthetics orders under the contract. As in the case of the proposed rule and this final rule, use of the Medicare pricing in the RFP was in response to a VA Office of Inspector General (OIG) report that found that past acquisitions resulted in inflated and noncompetitive pricing. An orthopedic services provider challenged the use of the Medicare pricing structure in the RFP because those rates allegedly did not provide adequate compensation for the services. The GAO found that VA properly exercised its discretion under the relevant statutory authority, 38 U.S.C. 8123. Section 8123 is very broad and gives VA the authority to "procure" prosthetic appliances and necessary services in whatever manner the Secretary deems proper, without regard to other provisions of law. Although 38 U.S.C. 8123 provides broad procurement authority without regard to other provisions of law, the GAO's holding did not rest solely on this basis. Rather, the GAO explained that the circumstances, particularly VA's broad grant of procurement authority, provided no basis for questioning the RFP's provisions. In particular, the GAO stated that "it is not unduly restrictive of competition for the agency to predesignate pricing in order to protect legitimate government interests." *See* Orthopedic Servs., Inc., B–247695, June 30, 1992, 92–1 CPD ¶ 547.

As mentioned above, a 2006 VA OIG report, No. 05–03037–107, described in the proposed rule, found that establishing payment rates is necessary to ensure consistent, predictable medical costs and control expenditures. In addition, unlike the RFP examined by the GAO, the Medicare prices prescribed by § 17.56(a)(2) are not ceilings per se, but rather the default price that must apply when no other rate has been negotiated. Thus, existing authority actually encourages the development of rates through regulation as a matter of consistent government practice and protection of the public fisc.

Notwithstanding our disagreement with the commenters that we lack authority to set rates via regulation, including for the individual authorizations that we have been providing before we proposed to revise § 17.56, the comments generally reflect that the proposed rule language was confusing. It did not sufficiently distinguish negotiated rates from the default rates that generally apply to individual authorizations. It also seemed to state that our authority for individual authorizations was something other than FAR/VAAR. As noted above, we have revised the final rule to eliminate references to the FAR and VAAR and to otherwise clarify the hierarchical payment structure that we stated in the proposed rule. These changes are not departures from our intent in the proposed rule text and we believe that they will eliminate the confusion and clarify the meaning and effect of the final rule.

Some commenters argued that Congress could not have intended to grant VA the authority to use Medicare rates under 38 U.S.C. 1703 because Congress explicitly authorized VA to set maximum payable rates in emergency situations under section 1725, but did not provide the same authorization in section 1703. In other words, the commenters state that the specific authority in section 1725 eliminates the possibility of implicit authority in section 1703.

There are two problems with this logic. First, as explained above, there is no need for a specific grant of authority in section 1703 because VA's contractual authority extends to VA's authority to pre-establish prices through regulation as a contractual "term" where specific rates are not otherwise negotiated. Second, the final rule does not set a maximum rate. The explicit authority in section 1725 to set maximum rates for emergency care episodes does not speak to whether VA may include in a regulation a default contractual rate for different, non-emergent services. Further, section 1725 applies only to emergent care rendered in non-VA facilities, a context in which pre-negotiated contracts are not practical. Thus, the explicit authority to set a maximum rate makes sense in this narrow context and should not be compared with the broader contracting authority in section 1703.

Related to challenges to VA's statutory authority, one commenter opined that § 17.56 is inconsistent with 38 CFR 17.52 and VA Directive 2007–025 because § 17.52 authorizes individual authorizations for medical services in non-VA facilities only when demand is for infrequent use and VA Directive 2007–025 states that dialysis should generally be authorized under a contract rather than fee for service. The rule is not inconsistent with 38 CFR 17.52 or VA Directive 2007–025. First, § 17.52 implements section 1703, which establishes that VA may contract with non-VA providers. Section 17.56 describes what payment methodology VA will apply in a given circumstance. As previously discussed, the inclusion of individual authorizations in § 17.52 demonstrates VA's broad interpretation of the word "contract" in section 1703. The fact that § 17.52 mentions individual authorizations does not make § 17.56 inconsistent for describing the payment rate that will apply in the absence of a negotiated contract. Second, in the context of dialysis services, VA's individual authorization authority applies because it is in fact infrequent that non-VA dialysis providers provide services to veterans under § 17.56. The veteran population that is served by these non-VA facilities is quite small when compared to the general population. In fact, some commenters indicated that they only had four total veteran dialysis patients annually. VA does not consider such usage to be "frequent." To the extent that these individual patients generally require repeated treatments, this is not the sort of "frequency" that we intended to govern through the § 17.52 reference to infrequent use—that regulation is clearly discussing the frequency of facility-wide use of non-VA providers

and not the use of non-VA providers to provide care to a particular individual.

Further, 38 CFR 17.56 is not inconsistent with the exhortation in VA Directive 2007–025 that dialysis care "should generally be authorized under a contract rather than on a fee for service basis." This language does not bar VA from using a means other than a long-term contract for the provision of dialysis care; it merely expresses non-binding agency guidance regarding the policies existing prior to this final rule. Moreover, the Directive is somewhat misleading, in that it suggests that individual authorizations under § 17.56 are not contracts. As previously explained, individual authorizations involve VA's offer via the appropriate referral form, and the provider's acceptance via delivery of services. Finally, if the VA Directive is at all inconsistent with our regulation, the regulation, which has been properly promulgated under the Administrative Procedure Act, and is therefore binding on VA and the public, clearly takes precedence. Hence, we do not make any changes based on these comments.

Comments That the Proposed Rule Did Not Comply With Executive Order 12866

Several comments raised economic concerns about the regulation. In particular, several commenters opined that the proposed rulemaking did not comply with Executive Order 12866. To the extent that the commenters challenge this rulemaking on Executive Order 12866 compliance grounds, we note that section 10 of the order explains that it "is intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States." The Office of Management and Budget (OMB) is solely responsible for enforcing the order, and OMB approved the proposed rule as being in compliance with the order. Therefore, we make no changes based on these comments. However, to the extent that the comments citing Executive Order 12866 address economic or other substantive concerns about the rulemaking, we address them elsewhere in this document.

Economic Concerns Raised by Commenters

The majority of the 18 comments received in connection with this rulemaking concerned the payment rate for dialysis treatment, the impact of the rule on small dialysis providers, whether VA would adopt various adjustments made to the Medicare schedule for dialysis care, and whether VA should phase-in the proposed payment rate for dialysis treatment.

As discussed in the proposed rule, VA intends to reimburse providers using the applicable Medicare fee schedule or prospective payment system as a standalone reimbursement method. VA considers Medicare's fee schedules and prospective payment systems as independent "fair market value" reimbursement without any consideration to cost reporting. Included in these fee schedules and payment systems are several items described in some comments as "adjustments." Again, if the "adjustment" is part of the Medicare schedule or payment system, then VA will apply it. Additionally, if a Medicare schedule is implemented by the Centers for Medicare & Medicaid Services (CMS) gradually, such as through a "phase in" approach, then our rule would apply the payment amount due according to the phased-in schedule for the period in which the medical service was provided. The rule is clear in this respect. For example, under 42 CFR 413.239, which will be effective on January 1, 2011, Medicare has instituted a transition period during which treatment for ESRD provided from January 1, 2011, through December 31, 2013, will be either phased in at a "blended rate" that adjusts each calendar year or, at the provider's option, at a rate of 100 percent of the payment amount determined under the rate established under 42 CFR 413.215. See *Medicare Program; End-Stage Renal Disease Prospective Payment System,* 75 FR 49,030, 49,198 (Aug. 12, 2010). Thus, if a provider has opted with Medicare to be paid at the § 413.215 rate, that is the rate applicable to that provider and VA will pay for ESRD services using that rate. Providers who have not exercised that option will be paid at the phased-in "blended" rate. We are already developing appropriate procedures to adjust payment rates for ESRD service providers who exercise this option, and we will not have any difficulty identifying these providers and paying them at the appropriate rate. Indeed, this is exactly what is contemplated by the reference in § 17.56(a)(2)(i) to "[t]he applicable Medicare fee schedule or prospective payment system amount * * * for the period in which the service was provided".

Notwithstanding the transition period for ESRD implemented by CMS in its regulations, several commenters urged VA to separately phase-in its adoption of the Medicare fee schedule. The commenters suggested that a phase-in by VA would lessen the disruption caused by the transition contained in the Medicare ESRD rates. For the reasons discussed in the following sections, we do not believe that any phase-in beyond that contemplated by the Medicare rates themselves is appropriate or necessary.

Moreover, as explained in the proposed rule, VA will not include any post-schedule adjustments made by CMS, such as end-of-year adjustments. As we explained in the proposed rule, due to the relatively small numbers of veterans impacted compared with the size of the Medicare program, we believe these end-of-year cost adjustments have minimal impact and will be cost-prohibitive for VA to execute.

One commenter discussed the effect of this rule on medical schools, noting that VA often contracts with teaching hospitals and medical schools at rates exceeding Medicare or VA fee schedules due to considerations such as impact on training programs. A few commenters also asked how this rule would affect sharing agreements with non-VA facilities made pursuant to 38 U.S.C. 8153, which provides VA with enhanced sharing authority to contract for health care resources. One commenter also asked whether VA will continue to follow VA Directive 1663, which provides special rules and policies for implementing and managing sharing agreements under section 8153.

In response to the above comments, we note that VA will continue to follow Directive 1663. This final rule applies only to payments for non-VA health care services purchased under 38 U.S.C. 1703. As such, health care resources contracted for under 38 U.S.C. 8153 are not affected by this rule. We will continue to follow VA Directive 1663 for negotiating contracts with medical schools.

Several commenters stated that § 17.56 will have a significant impact on small dialysis providers. We are sympathetic to the needs of small health care providers and the potential effect of decreased VA payments on these providers. However, we also dispute at least some of the basis for the comment. In the proposed rule, we recognized that adopting the Medicare payment system for dialysis could lead to a 39 percent decrease in VA's overall outpatient dialysis facility expenditures. We recognize that this effect will be greater on smaller providers who receive VA funds. However, we also explained that the benefits of this savings to our nation's veterans and to the American people, as well as our adoption of the national "standard" rate (*i.e.,* the

Medicare rate) for government-reimbursed private health care, outweighed the potential impact on some small dialysis providers. So long as veterans continue to have access to care (see below), we believe that it would not be a responsible use of VA funds to continue to pay a rate higher than that paid by other Federal agencies simply to subsidize these providers or to address perceived financial performance issues in other lines of business. Concerns and comments about whether the rates adopted by CMS are adequate or appropriate as a general matter have been addressed by CMS in their final rulemaking. *See* 75 FR 49030 (Aug. 12, 2010). In addition, we have addressed throughout this final rule the adequacy and propriety of adopting those rates specifically for care provided to veterans.

Again, we are adopting Medicare rates as the uniform standard for Federal government payment for care purchased from private sector providers. Congress has established a number of processes for monitoring the adequacy of payment rates in Medicare and for providing input on potential updates and changes in Medicare, and providers with underlying concerns about Medicare's payment rates should address those concerns to CMS and other entities such as the Medicare Payment Advisory Commission (MedPAC). Further, Medicare's new prospective payment system for dialysis services, starting in 2011, is expected to recognize the unique needs of low-volume providers by including adjustments to the CMS schedule for low-volume providers. VA would implement this higher payment for low-volume providers as it is implemented by the Medicare payment system, including, as noted above, any phase-in of that payment system. Again, the final rule clearly states that VA will apply the rate required by that payment system.

In addition, our analysis in the proposed rule shows that VA is not a significant source of revenue for any providers. In fact, a majority of dialysis providers do not treat VA-referred patients. A 2008 CMS report to Congress on ESRD payments documents some 315,000 patients receiving chronic dialysis services paid for by CMS (A Design for a Bundled End Stage Renal Disease Prospective Payment System, *available at http://www.cms.gov/ESRDGeneralInformation/Downloads/ESRDReportToCongress.pdf).* In contrast, VA typically purchases these services for approximately 9,000 patients. This reinforces the conclusion that the number of VA-funded patients in the community represents only a small portion of the total number treated. In addition, it is unreasonable to expect VA to pay at a significantly higher rate than the rate at which CMS reimburses.

Commenters also stated that the current state of the economy, specifically unemployment, has led to a decrease in the number of privately insured dialysis patients, further magnifying the impact of additional change to the current VA payment structure (because private insurers pay more than the Medicare rate). Again, we recognize that this is a valid concern, but the solution is not higher rates of payment solely for treating our nation's veterans (so long as they continue to have access to care). VA's responsibility to our nation's veterans does not include a duty to address changes in the national economic climate. We also note that due to national health reform efforts, such as The Affordable Care Act, Public Law 111–148, the number of privately insured patients should, in fact, increase.

One comment stated that making contract negotiations contingent upon the contracted rates being lower than Medicare would render many providers economically unable to bid. Nothing in the final rule restricts negotiations of possible payment amounts. Moreover, we note that virtually every non-VA provider in the United States does accept Medicare patients and therefore does accept payment at the Medicare rate. One comment recommended changing the language in proposed § 17.56(a)(2)(iii)(A) to expressly state that the applicable "geographically adjusted" Medicare rate will apply. Because Medicare rates take into account the geographic location of the provided service, we decline to make this change.

Concerns Raised by Commenters Regarding Access to Care, Particularly to Dialysis Treatment

Several commenters asserted that the effect of this rule on low-volume dialysis providers will force them to refuse to accept VA patients, or will lead to the closure of entire low-volume dialysis facilities. Similarly, commenters stated that because the rule will cause non-VA dialysis providers to close and/or refuse VA patients, veterans will have fewer scheduling options. Comments were that fewer scheduling options will require veterans to schedule their care for different times and potentially require veterans to travel greater distances to receive care, which could be detrimental to their health. The commenters opined that their concerns will be magnified for rural veterans.

VA takes this concern seriously, and we are strongly committed to ensuring that this final rule does not diminish access to care for the nation's veterans, including those who suffer from kidney disease. For three reasons, we do not believe that the concern about diminished access is justified. First, our analysis of the effect of this rule on the national non-VA dialysis provider community does not support that concern. ESRD services are currently provided to Medicare patients by private providers at the Medicare rate, and there is no evidence that these providers will refuse to continue to provide ESRD services to veterans simply because the payment rate will now be the same as the rate for Medicare patients. On the contrary, the historical record suggests that payment of the Medicare rate has not led providers to deny care to Medicare patients. In its March 2010 report, *Report to the Congress: Medicare Payment Policy,* MedPAC found that most payment adequacy indicators for dialysis services are positive and that Medicare beneficiaries continue to have good access to care for dialysis services. (available at *http://www.medpac.gov/documents/Mar10_EntireReport.pdf*) In adopting Medicare's payment rates for dialysis, we expect that VA beneficiaries should similarly have good access to care. This conclusion is fortified by the fact that, under the Medicare program, CMS has instituted a transitional period for ESRD payments.

Second, we note that CMS has finalized a new bundled prospective payment system, which will be effective in 2011, and which will explicitly include adjustments based on different geographic regions and for low-volume providers. 75 FR 49030, 49198 (Aug. 12, 2010). When Medicare implements these adjustments, they will be applied under § 17.56 because they will be part of the Medicare fee schedule that will be adopted by this rule. Such adjustments should help to ensure that this final rule does not have adverse effects on access to care, including in the rural areas that have been mentioned by some commenters.

Third, and finally, all existing contracts will continue to be honored, and we retain the right to contract with specific providers at specialized rates. We will exercise our right to enter into contracts with providers, including at rates higher than the Medicare rates, if and when necessary to ensure that veterans, including veterans who live in rural areas, have access to quality care.

We reiterate that ESRD services are currently provided to Medicare patients by private providers at the Medicare rate, and there is no reason to believe these providers will refuse to continue to provide ESRD services to veterans simply because the payment rate will now be the same as the rate for Medicare patients. For all of the reasons discussed above, we do not believe that adopting the Medicare rates will jeopardize the ability of our nation's veterans to obtain necessary health care in general, or specifically for ESRD. We are prepared to take appropriate steps to address that concern if and when it arises.

Similarly, some commenters believe that the rule will cause a decline in the quality of care administered by private dialysis providers. Medicare patients represent the bulk of the country's dialysis patients, and we are simply adopting the same rates that will be paid by Medicare. Medicare's January 1, 2011 implementation of the prospective bundled payment system, which VA adopts in this final rule, includes a significant expansion in case-mix adjustments. 75 FR 49030 (Aug. 12, 2010). Because these case-mix adjustments are part of the Medicare payment system, VA will be including them in its use of the Medicare payment rates. There is no evidence to suggest that the majority of patients who receive services under the Medicare umbrella are expected to see a decline in quality of care. VA adopting this same payment rate should not decrease quality of care.

One commenter also indicated concern that the proposed rule will lead to an increase in the illegal practice of "split invoicing" or "balance billing," whereby private providers bill patients separately and on top of Medicare or VA payment schedules. By law, VA's payment represents payment in full; it is illegal for providers to "balance bill" or "split invoice" VA beneficiaries for an amount above VA's allowed charge. Anticipated violations of this law are not a valid basis for a policy determination; however, they may affect implementation or lead to greater oversight through procedural methods. VA will not allow the potential for illegal activity to prevent us from promulgating a valid rule that conforms to national health care policy. We make no changes based on this comment.

Comments That the Quality of VA Services Will Decline

Commenters indicated that because some dialysis providers may refuse VA patients, VA will be forced to take on more dialysis patients at its own Medical Centers. Commenters opined that this will overwhelm VA's facilities, resulting in a lower quality of care than what would be provided by non-VA providers. We make no changes based on these comments. For the reasons explained previously, we do not think that the payment changes will negatively impact access to care or that VA will be forced to take on more dialysis patients. Further, we do not expect this to impair veterans' access to non-VA dialysis services. We also disagree with the commenter's assertion that VA facilities would provide a lower quality of care relative to non-VA providers under the final rule.

Comments About VA's Billing Practices

Several commenters believe that VA is not prepared to adopt the Medicare reimbursement scheme set to take effect in 2011. They cite to a 2009 internal audit conducted by VA OIG that shows that VA has improperly reimbursed dialysis providers under its current Fee Based program, which according to the commenters is easier to administer than the proposed changes.

VA has taken action to improve our payment practices based in part on the results of the OIG audit. To assure we implement timely and accurate payment processing under this final rule, VA will follow its predecessors at CMS and the Department of Defense (DoD) (in the context of the TRICARE program), by hiring a third party with expertise to accurately price claims (VA will continue to pay after the third party pricing) under the Medicare payment system. This contractor will be responsible for determining the appropriate Medicare rate, including the contemplated changes to the dialysis rate that we expect to take effect in 2011. This should ensure that reimbursement is properly calculated, as both CMS and TRICARE have had success with this approach.

The use of contractors also should serve as a response to comments that we should document how we will ensure compliance with the final rule, including that providers receive accurate and timely payment under the final rule because CMS and TRICARE have successfully addressed such potential problems in this same manner.

In addition, because CMS had not yet published its final rule during the public comment period for VA's proposed rule, the commenters believed that VA could not adopt the new payment system with respect to the 2011 schedule changes. Since the submission of the comment, CMS published a final rule titled "Medicare Program; End-Stage Renal Disease Prospective Payment System," which amended 42 CFR parts 410, 413, and 414. 75 FR 49030 (Aug. 12, 2010). The rule adopts the Medicare fee schedule in effect on January 1, 2011, and thereafter; VA will be required under this rule to immediately adjust its fees to adopt the CMS prospective bundled payment system on the effective date of the rule. We make no changes to the rule based on this comment because the publication of the CMS final rule addresses the concerns presented by the commenter.

One commenter asserted that VA's claims process is more expensive and administratively burdensome than that of Medicare, and that the historical VA rates better cover these additional costs. Specifically, the commenter asserted that VA's preauthorization requirement, inconsistency in accepting electronic billing, payment processing delays, and inconsistency in making electronic payments all contribute to higher costs for providers. The commenter suggested that the proposed rule "would result in a reduction in provider reimbursement far in excess of the mere rate change from VA to Medicare" and requested that VA exclude laboratory services from the rule. We will not make any changes based upon these comments.

The purpose of this rulemaking is in part to facilitate standardization in Federal government payment for medical services. We disagree with the allegation that VA's requirement of treatment authorization for a non-VA provider to receive payment is burdensome to obtain, because VA's practice is to pre-authorize veterans, effectively removing any potential burden on providers. Regarding processing delays and the need for more consistency in electronic billing and payments, it is our view that the first step toward the efficiency the commenter seeks is to standardize as much as possible the amount being billed and paid by VA. We have carefully considered and rejected the commenter's suggestion that we continue the inefficiencies associated with current methodology while we nonetheless strive to become more efficient. Moreover, we note that VA is actively improving its billing and payment practices. VA is currently transitioning to an improved claims processing system, which should hasten payment of claims and enhance VA's electronic payment remittance and EFT capabilities. With this final rule, VA will actually have an even greater opportunity to reduce administrative costs by adopting a standardized payment methodology. This will allow VA to better identify and implement best practices developed by CMS and

other third-party payers. Accordingly, we intend that any additional cost currently associated with billing VA for providing care to veterans will be removed upon implementation of the final rule.

VA Should Exempt Certain Services or Otherwise Modify Its Adoption of the Medicare Rate

Some commenters stated that VA should exempt dialysis treatments and/or laboratory services from the adoption of the Medicare payment system. We make no changes based on these comments. Excluding any services from the rule is inconsistent with one of the goals of this rule, which is to align VA reimbursement with the government standard. Moreover, there is no evidence to support the comment that the proposed rule would create an administrative burden on laboratory service providers. Virtually all of these providers currently use the Medicare payment system to bill Medicare patients, and will be required to use the CMS prospective bundled payment system beginning on January 1, 2011. Because these providers must implement the new Medicare schedule, applying it to VA-referred veterans should not present an undue administrative burden.

Commenters also stated that VA should consider establishing a rate not tied to Medicare. Commenters suggested alternatives to the Medicare rate, such as allowing the negotiation of non-standard contracts in the event of special circumstances like transfers from VA facilities to non-VA facilities of medically complex patients; implementation of a coordinated-care plan like the Contract Care Coordination Recommendations of VA's Independent Budget, FY 2011; and a payment regime that would incentivize more participation by non-VA health care providers. We do not make any changes based on these comments. Again, one of the goals of this rule is to align our payment structure with the government standard. Adopting a different rate would defeat this purpose.

As to incentivizing participation by non-VA providers, VA retains its ability to negotiate contracts under this rule and may consider special circumstances like those that the comments raised, to the extent allowable under the FAR and VAAR contracting authorities. Similarly, VA has included care coordination requirements in some of its recent contracts with community health care providers, and continues to seek opportunities for improved coordination of care. These efforts are not precluded by this rule. We make no changes based on these comments.

Another comment was that VA should evaluate the cost of treating patients in its own centers and compare it to the Medicare rate. One commenter suggested that VA would incur greater costs if it were forced to accept more dialysis patients in house. As previously discussed, we reject the premise that the rule will cause decreased access to care. Another commenter asserted that the Medicare rate for dialysis is less than the amount that VA calculates as the cost of care at VA facilities. Any number of variables may affect the cost of providing care; therefore, it is not clear that costs of providing dialysis at VA facilities can be properly compared to costs of providing dialysis at non-VA facilities. In any event, this comparison is not relevant to our policy decision to pay non-VA providers at the national standard, Medicare rate. Moreover, as noted repeatedly in this notice, Medicare may adjust the rate payable for dialysis to address pricing accuracy.

Another comment was that VA should not implement the contemplated revisions to the rule until CMS has finished phasing in the new Medicare payment system for dialysis, which CMS has proposed to do over a 4-year period. We do not intend to wait until after Medicare's 4-year phase-in period to adopt the current CMS rates for purposes of establishing a national standard rate. If necessary, we will address any problems or issues uncovered by CMS during the 4-year period, particularly if these problems are unique to our veteran population or are not addressed by CMS. There is no need to wait until their phase-in is complete.

Comments That VA Relies Upon Erroneous and Inaccurate Facts

A commenter stated that VA has significantly misinterpreted the data that it relied upon in the proposed rule. As a result, the commenter believes that VA incorrectly determined that the impact on dialysis providers would be minimal, and VA has not adequately considered reasonable alternatives. Specifically, the commenter stated that VA erroneously proposed to pay for dialysis services using 2008 Medicare claims data that reflect the soon-to-be-outdated composite rate and payment rates for separately billable items.

We make no changes based on these comments. VA has correctly relied upon the data presented in the proposed rule to determine the number of veterans who receive dialysis treatment at non-VA facilities relative to the total population of dialysis patients receiving such care from private providers. We have addressed each alternative proposed in the comments, and have demonstrated VA's strategy to incorporate Medicare's 2011 pricing change for dialysis. In addition, VA cannot simulate the specific cost impact of Medicare's 2011 revision to the dialysis rate because Medicare has not yet implemented the prospective bundled payment system. Therefore, use of the 2008 Medicare claims data was proper as this was the most recent available data.

Another commenter stated that the smallest dialysis provider in New Hampshire received more than $200,000 in payments, so the claim in the proposed rule that 95 percent of vendors received less than $150,000 and 82 percent received less than $50,000 is incorrect. The data relied upon by VA for our statement in the proposed rule—which considered this specific facility—were for fiscal year 2008. We believe that the discrepancy between the commenter's calculation and VA's calculation is explained by the fact that (1) VA's calculation did not include costs for lab services and services purchased under competitive contracts, and (2) VA calculated by calendar year whereas the commenter calculated by fiscal year. Inclusion of these costs and calculation of total payments by calendar year (rather than fiscal year) account for the discrepancy between the commenter's records and VA's calculation that 95 percent of providers received less than $150,000 and 82 percent received less than $50,000.

In fact, using the commenter's own calculations actually supports our overall rationale in adopting this final rule. The commenter stated that in 2008 they provided a total of 6,501 dialysis treatments at an average cost of $264.85 per treatment. 5,417 treatments were for Medicare patients, 349 treatments were for Medicaid patients, 160 treatments were for veterans, and payment for the remaining 575 treatments were from unlisted sources. Based on the comment, the provider received payment from VA of over $200,000 for providing dialysis care costing approximately $42,376. This data supports the cost-saving rationale for use of the Medicare rate, and demonstrates that the Medicare rate will be sufficient to support the community of private dialysis providers. VA predicted a 39 percent decrease in the rate at which it reimburses providers for dialysis care, which would still reimburse this specific provider far more than the estimated $264.85 cost of care per patient. Thus, the commenter's own data shows that the proposed CMS

rates would be adequate, and that the commenter will continue to receive significant profits from treating VA patients.

A Commenter Requested That VA Define "*Repricing Agent*" *To Clarify Which Payors Are Encompassed in the Term*

We agree with the comment and have changed § 17.56(a)(2)(ii) to define a "repricing agent" as follows: "For the purposes of this section, repricing agent means a contractor that seeks to connect VA with discounted rates from non-VA providers as a result of existing contracts that the non-VA provider may have within the commercial health care industry."

Repricing is a program that allows VA to share in savings available in managed care networks by utilizing contracted rates currently available in the commercial industry and paying a contracted repricing agent a portion of the savings. The use of the repricing agent provides VA with access to economical community-based vendor contracts that provide cost avoidance for VA. Non-VA care claims submitted to VA for payment are sent to the repricing agent to determine if a lower rate can be utilized.

Comment That VA's Fee Schedules Should Be Readily Available to the Public

The final rule continues to provide, as one basis for calculating the payment amount, the "75th percentile" schedule used under § 17.56 prior to its revision by this rulemaking. A commenter requested that this fee schedule be made available to the general public. Currently, VA field offices each maintain a separate fee schedule and individual fee schedules are currently available to the public upon request. The Medicare fee schedules and prospective payment system rates are already available to the general public. However, the rates calculated using the 75th percentile method are calculated and applied at the local level, and can be obtained from local offices. Additionally, after the effective date of this final rule, VA will add complete and accurate information to the public on VHA's Web site. This should further address the commenter's concern.

Comment That VA Has Not Made Payments Consistent With the Maryland Waiver, and Should Reconcile Discrepancies

The proposed and final rule text clearly states that VA will comply with the terms of any Medicare waiver. To the extent that the commenter is concerned about VA's past performance, this is beyond the scope of this rulemaking.

Comments That VA Should Integrate Care With Non-VA Dialysis Providers, in Which Health Information From Non-VA Providers is Easily Exchanged With VA

We agree with the comment, but make no changes to the final rule. VA takes every opportunity to provide quality care to veterans and strives to assure those same veterans receive quality care from non-VA providers. VA is currently planning pilots for increased clinical information sharing with community providers, and this rule does not preclude VA from implementing electronic health information sharing policies.

Home Health Care and Hospice Care

As noted above, in the proposed rule, we indicated that the pricing methodology adopted by this rule would be used in establishing payment rates for all non-VA inpatient and outpatient health care professional services and other outpatient services, including hospice care and home health services. However, in reviewing implementation strategies and internal procedural practices related to the payment of hospice care and home health services through means other than a contract, we have encountered significant practical problems that prevent immediate implementation of this new methodology. These problems relate to separate administration of hospice care and home health services by the Veterans Health Administration's Office of Geriatrics and Extended Care, which uses separate methods for forming agreements for these services, and challenges regarding information technology systems necessary to move to the new Medicare rate, but do not relate to the actual payment amounts for these services. Such amounts would generally be unchanged by this rulemaking because the vast majority of these services are paid through a contractual mechanism (and are therefore exempted under § 17.56(a)(1)). However, we estimate that there may be about 100 providers who are not paid through a contractual mechanism and therefore who would have been affected by this rulemaking.

Given separate administration of hospice and home health services under separate VA guidance, we have determined that these providers did not receive adequate notice regarding the intended effect of the proposed rule or of the need for some delay in implementation of the rule so that VA may modify its systems. We will promulgate, as soon as possible, a proposed rule to make § 17.56, as revised by this notice, applicable to these providers. Therefore, we have added to paragraph (a) of the final rule an exception for these two services.

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 provisions constituting a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). Non-VA health care providers currently bill VA using uniform billing forms CMS–1450, OMB Control No. 0938–0997, and CMS–1500, OMB Control No. 0938–0999. This practice will not be altered or amended.

Regulatory Flexibility Act

The Regulatory Flexibility Act requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, Ambulatory Surgery Centers, and other providers subject to this rule are considered to be small entities, either by being nonprofit organizations or by meeting the Small Business Administration (SBA) definition of a small business, as codified in 13 CFR 121.201. Therefore, the Secretary has determined that this final rule would have a significant impact on a substantial number of small entities and therefore completed a final regulatory flexibility analysis, which is discussed in "Executive Order 12866 and Regulatory Flexibility Act."

Executive Order 12866 and Regulatory Flexibility Act

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 Executive Order classifies a regulatory action as a "significant regulatory action," requiring review by the Office of Management and Budget (OMB) unless OMB waives such review, if it is a regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

VA has examined the economic, interagency, budgetary, legal, and policy implications of this final rule and has concluded that it is a significant regulatory action under Executive Order 12866 because it is likely to result in a rule that may have an annual effect on the economy of $100 million or more.

VA followed OMB circular A–4 to the extent feasible in this analysis. The circular first calls for a discussion of the need for the regulation. The preamble above discusses the need for the regulation in more detail.

Need

Under 38 U.S.C. 1703(a), "[w]hen [VA] facilities are not capable of furnishing economical hospital care or medical services because of geographical inaccessibility or are not capable of furnishing the care or services required, the Secretary, as authorized in [38 U.S.C. 1710], may contract with non-[VA] facilities in order to furnish" certain hospital care and medical services to veterans who qualify under 38 U.S.C. 1703. Medicare is the largest U.S. Federal health care payer and is recognized as the Federal health care industry standard for reimbursement rates. Providers, particularly the medical facilities affected by this rule, are familiar with Medicare payment methodologies. Indeed, VA currently uses Medicare methodologies in connection with in-patient treatment and physician and non-physician professional services. Moreover, two separate audits by VA's Office of Inspector General concluded that clarification of VA's regulations governing payment of outpatient facility charges is necessary. *See* VA OIG Reports 08–02901–185 (2009) and 05–03037–107 (2006). As such, we believe the adoption of Medicare rates will help ensure consistent, predictable medical costs and will help control costs. Thus, we believe that adoption of this rate is important to both VA and the general public.

Impact

We received a number of comments objecting to the proposed rule due to a perceived adverse impact on small businesses, specifically low-volume dialysis providers. Commenters argued that due to the reduction in the rates dialysis providers currently charge VA and the Medicare rate that VA proposed to adopt, many providers will be forced to refuse care to veterans while a great deal of providers, particularly in rural areas will close down altogether. These comments are discussed in greater detail in the preamble above.

In general, the final rule will impact the following providers classified as small businesses: Freestanding emergency and ambulatory surgical centers with revenues less than $9.0 million, independent diagnostic centers with revenues less than $12.5 million, and hospitals and kidney dialysis centers with revenues less than $31.5 million. A precise estimate of the number of small entities that fall within the rule is not currently feasible. See the below "Benefits-Cost Analysis" discussion for additional information concerning the economic impact of this final rule.

Benefits-Cost Analysis

We received comments asserting that the benefits-cost analysis was inaccurate or too broad because it overlooked the potential adverse impact on certain low-volume dialysis providers, and disregarded the overall cost of providing dialysis treatment. VA contracted with an independent consultant to conduct and analyze the benefits-cost analysis in more detail. The VA's estimated total cost savings amount published in the proposed rule has been revised to show the slightly higher amount provided in the contractor's analysis. The comments regarding the benefits-cost analysis are addressed fully in the preamble above and in the Accounting Statement below.

Alternatives

We received a number of comments suggesting that VA use alternative pricing mechanisms for different geographic regions in order to provide more equitable payments to dialysis providers in rural areas. Several commenters suggested alternative approaches including a phase-in of the CMS fee schedule, geographically adjusted rates, and different rates for low-volume providers. We have addressed these comments in detail in the preamble above.

Approximately 1.6 percent of the total U.S. population are veterans who utilize the VA Health Care System. Of the total number of veterans who utilized the VHA Health Care System in fiscal year 2008, VHA preauthorized non-VA outpatient hospital services for approximately 5.4 percent of veterans, 2.5 percent used community hospital emergency rooms, 0.8 percent used freestanding ambulatory surgery centers, 0.7 percent used independent laboratories, and 0.1 percent were authorized care at end stage renal disease treatment centers at VA expense. We believe that the impact of veterans authorized non-VA health care services at VA expense in the local health care market is minimal, as illustrated in Table 1.

TABLE 1—PERCENT OF VETERANS UTILIZING VA HEALTH CARE SYSTEM

State	FY 2008 total population	FY 2008 total veteran users	Percent of total veteran users/total U.S. population
Alabama	4,692,977	94,426	2.0
Alaska	689,791	13,826	2.0
Arizona	6,630,722	114,126	1.7
Arkansas	2,910,777	80,831	2.8
California	37,873,407	369,346	1.0
Colorado	4,962,478	68,628	1.4
Connecticut	3,550,231	50,373	1.4

TABLE 1—PERCENT OF VETERANS UTILIZING VA HEALTH CARE SYSTEM—Continued

State	FY 2008 total population	FY 2008 total veteran users	Percent of total veteran users/total U.S. population
Delaware	885,956	13,099	1.5
District of Columbia	589,366	8,894	1.5
Florida	19,119,225	420,202	2.2
Georgia	9,863,250	139,428	1.4
Hawaii	1,312,372	18,706	1.4
Idaho	1,549,062	32,886	2.1
Illinois	13,177,638	168,982	1.3
Indiana	6,468,433	111,562	1.7
Iowa	3,042,015	66,833	2.2
Kansas	2,828,255	56,131	2.0
Kentucky	4,295,044	90,718	2.1
Louisiana	4,500,627	79,472	1.8
Maine	1,349,506	37,359	2.8
Maryland	5,743,662	70,754	1.2
Massachusetts	6,518,184	77,112	1.2
Michigan	10,314,853	119,290	1.2
Minnesota	5,357,700	95,409	1.8
Mississippi	2,986,953	65,369	2.2
Missouri	5,977,318	122,411	2.0
Montana	965,024	29,279	3.0
Nebraska	1,814,105	42,322	2.3
Nevada	2,730,425	53,423	2.0
New Hampshire	1,343,347	25,220	1.9
New Jersey	8,890,186	75,882	0.9
New Mexico	2,029,633	44,824	2.2
New York	19,554,879	225,452	1.2
North Carolina	9,231,191	166,138	1.8
North Dakota	652,934	16,954	2.6
Ohio	11,633,295	190,646	1.6
Oklahoma	3,672,886	79,735	2.2
Oregon	3,814,725	79,168	2.1
Pennsylvania	12,631,267	266,529	2.1
Rhode Island	1,078,084	19,174	1.8
South Carolina	4,479,461	98,624	2.2
South Dakota	809,862	28,291	3.5
Tennessee	6,244,163	114,393	1.8
Texas	24,627,546	371,259	1.5
Utah	2,677,229	29,042	1.1
Vermont	636,472	14,163	2.2
Virginia	7,899,205	114,076	1.4
Washington	6,628,203	91,233	1.4
West Virginia	1,836,864	56,541	3.1
Wisconsin	5,701,620	104,787	1.8
Wyoming	526,857	16,884	3.2
Totals	309,299,265	4,845,786	1.6

Table 1 above shows the relationship between the gross population of each state compared to veterans utilizing the VA health care system. It is clear that the veteran population utilizing VA health care services is fairly consistent by state. The FY 2008 Total Population (Table 1) was obtained from statistics published by the U.S. Census Bureau. The total veteran users, is the number of unique veterans who utilized the VA health care system during FY 2008 for all or a portion of their health care needs. This number was obtained from the National Center for Veterans Analysis and Statistics geographic data. The number includes veterans treated at VA medical centers, clinics, CBOCs, mobile clinics, and care purchased from other Federal facilities and from the private sector.

Based on the constant percentage we do not believe the final rule will have considerable impact on any one geographic region. As a result of this, we believe the reduced reimbursement rates for non-VA health care services will follow a similar pattern and not result in a considerable impact on any one geographic region. As such, we do not believe that there is a reasonable need for alternatives to adopting Medicare payment methodologies.

Finally, we do not believe that there is a significant risk to adopting the Medicare fee schedules or payment systems. Although it is theoretically possible that some providers may refuse to treat veterans due to lower reimbursement rates, those same providers are already accepting patients under Medicare and we do not believe that they will refuse to treat veterans. Moreover, the first payment option set forth in the final rule would be "[t]he amount negotiated by VA and the provider" consistent with Federal contracting principles. Because VA and providers retain the ability to negotiate a fee that is greater (or lower) than the Medicare rate, VA will be able to ensure that veterans in remote areas continue to have access to care should a particular facility refuse to accept Medicare rates. However, because Medicare is the Federal health care industry standard

payer, we do not believe that this will be a significant issue.

Accounting Statement

VA contracted with an independent contractor to conduct a more detailed analysis of the expected savings under the Medicare outpatient payment methodologies described in the proposed rule. As previously mentioned, VA's estimated dialysis savings have been revised from the proposed rule to reflect a more accurate analysis that was conducted by that independent contractor. VA has adopted the independent contractor's analysis and the details of the study are discussed in greater detail below. The use of the first person "we" below refers to work conducted by the contractor and work done by VA.

The analysis consists of the following:

- Clinical Lab services provided through VA purchased care to VA beneficiaries;
- Outpatient Dialysis/End Stage Renal Disease (ESRD) services provided to VA beneficiaries in non-VA facilities;
- Ambulatory Surgery Center (ASC) facility charges for VA purchased care; and
- Hospital Outpatient Department (HOPD) and emergency room (ER) facility charges for VA purchased care.

Clinical Lab Services

We identified all clinical lab services provided through VA purchased care to VA beneficiaries in the first 6 months of calendar year 2008. We selected this period because the data was sufficiently complete. We then edited the data by removing outliers (claims paid under $1 or over $500) and eliminated a very small number of claims that were unable to map to zip codes or that had more than one unit of service on a line item. We also excluded claims that were paid under contracts with clinical labs or with certain managed care providers.

To estimate the impact of using Medicare's clinical lab fee schedule, we focused on the 100 clinical lab services (by CPT code) with the highest aggregate non-VA (purchased care) allowed amounts. These 100 codes accounted for about 86.5 percent of all non-VA clinical lab service costs. We calculated the impact of paying these non-VA clinical lab claims using Medicare's fee schedule as the maximum allowable charge. In calculating the impact of Medicare pricing, we excluded a small number of the top 100 CPT codes that are not on Medicare's lab fee schedule because Medicare pays these services using the Medicare physician fee schedule. We also excluded clinical labs at Maryland hospitals and critical access hospitals because they are not subject to the Medicare lab fee schedule. We also excluded physician claims marked with a modifier of 26. Our estimates accounted for Medicare's higher payments for clinical lab services at sole community hospitals. We also used the unique Medicare carrier rates for lab services where appropriate in individual locations.

We found that in 2008, VA paid an average of almost $49 per line item for clinical lab services for the top 100 VA purchased care clinical lab services. Under Medicare pricing, VA would pay an average of $11.47 for these claims. This represents a cost reduction of approximately 75 percent. We calculated a cost reduction of $53 million when we extrapolated the results of our analysis of the top 100 codes for the first 6 months of CY 2008 to all VA clinical lab services in CY 2008.

We did some further analysis of the 15 clinical lab codes with the highest VA purchased care volumes and found that these 15 clinical lab codes accounted for about one-half of the VA's payments for clinical lab services in the first 6 months of CY 2008. The cost reductions for these 15 codes ranged from 63 percent to 85 percent, which indicates that the allowed amounts under Medicare's pricing would be equal to 15–37 percent of the current VA allowed amounts. This indicates that the impact of using the Medicare clinical lab schedule will lead to a relatively homogeneous reduction in clinical lab payments.

IMPACT OF MEDICARE PRICING ON VA CLINICAL LAB CLAIMS, 2008

Payments under VA current method	Payments under Medicare pricing	Cost reduction	Cost reduction as a percentage of VA payments
$71.4M	$18.1M	$53.3M	74.6%

Outpatient Dialysis/End Stage Renal Disease (ESRD)

We identified outpatient dialysis services provided to VA beneficiaries in non-VA facilities in the first 6 months of calendar year 2008. We selected this period because the data was sufficiently complete. We focused on a subset of dialysis procedure codes and injectible drug codes that together accounted for the vast bulk of outpatient dialysis facility charges for care purchased by the VA. We edited the data to remove outliers (claims with very high or low paid amounts per unit of service). We eliminated the small number of dialysis procedure claims that had more than one unit of service. For dialysis drug claims, on the other hand, we eliminated claims that had only one unit of service because these injectible drugs are normally administered as multiple units of service. We also excluded claims that the VA pays through purchased care contracts.

We then calculated the impact of paying these non-VA dialysis claims using Medicare's dialysis facility pricing methods to set the maximum allowable charge (based on Medicare's composite rate for dialysis procedures and Medicare prices for the separately payable injectible drugs). For dialysis procedure claims, the available claims data does not include the patient case-mix data necessary to calculate the exact composite rate amount for each VA claim. However, a recent CMS analysis indicated that Medicare's national average composite rate payment was approximately $156 per dialysis session in 2007.[1] We assumed the same national average rate would be a reasonable estimate for VA except we increased the average rate to $157 to allow for modest inflation to 2008. For each specific claim, we then adjusted the national average amount using Medicare's geographic wage index adjustment for ESRD dialysis facility charges. For the injectible drug claims, we used Medicare's prices. For each claim, we then compared the original amount paid by VA to the price Medicare would pay, and from this comparison we kept the lesser amount as the final amount VA would pay for a given claim (the Medicare price would set the maximum charge for that claim, but in some cases the local VA facility might already have

[1] CMS, "Medicare Programs; End-Stage Renal Disease Prospective Payment System; Proposed Rule", **Federal Register**, Sept. 29, 2009, p. 49940.

negotiated a lower rate than the Medicare rate).

For the claims in our analysis, we found that with Medicare pricing the VA's outpatient dialysis facility expenditures would decrease by 39 percent. When extended to the universe of outpatient dialysis facility services for VA in 2008, we calculate a cost reduction of $68 million. The cost reductions for the dialysis procedures ranged from 21–35 percent for the three most common dialysis codes and the savings on injectible drugs ranged from 48–69 percent for the three most common codes. These estimated cost reductions may represent an upper-bound estimate because, although we do not anticipate any particular need to enter into contracts at rates higher than the Medicare rates to ensure access to services, the cost savings could be lower if that were required.

IMPACT OF MEDICARE PRICING ON VA FEE BASIS OUTPATIENT DIALYSIS FACILITY CLAIMS, 2008

Payments under VA current method	Payments under Medicare pricing	Cost reduction	Cost reduction as a percentage of VA payments
$175.9M	$107.7M	$68.2M	38.8%

Ambulatory Surgery Center (ASC)

We identified all Ambulatory Surgery Center (ASC) facility charges for VA purchased care in the first 6 months of calendar year 2008. We selected this period because the data was sufficiently complete. We then edited the data to remove claims from ASCs for clinical lab services and medical services (CPT codes with a value greater than 90000) because they are not paid using Medicare's ASC payment system. We also edited the VA purchased care claims data to eliminate physician services which would be paid using Medicare's physician fee schedule, based on CPT code modifiers and specialty codes. We also excluded claims that were paid under contracts with ASCs or with certain managed care providers.

To estimate the impact of paying these ASC claims using Medicare's ASC payment system we excluded ASC facility charges for surgeries that are not paid in ASCs by Medicare because they are considered "inpatient only" services.

Under its current pricing policies, we found that in 2008, the VA paid an average of about $431 in ASC facility charges to non-VA facilities for each ASC surgery. Under Medicare pricing, the VA would pay an average of $383. This represents a cost reduction of approximately 11 percent. When extended to the universe of ASC charges for VA purchased care in 2008, we calculated an aggregate cost reduction of $1 million.

IMPACT OF MEDICARE PRICING ON NON-VA ASC FACILITY CHARGES, 2008

Payments under VA current method	Payments under Medicare pricing	Cost reduction	Cost reduction as a percentage of VA payments
$11.0M	$9.7M	$1.3M	11.2%

We also focused on the facility charges for the 15 highest-volume surgeries done in purchased care for VA beneficiaries. We found that these 15 surgery codes accounted for almost 60 percent of the VA's payments for purchased care ASC charges in the first 6 months of CY 2009. The percentage changes under Medicare pricing for these 15 codes ranged from a reduction of 30 percent to an increase of 44 percent. Thus, using Medicare's pricing would result in some codes being paid more and some being paid less.

Hospital Outpatient Department (HOPD)

We identified all hospital outpatient department (HOPD) and emergency room (ER) facility charges for VA purchased care in the first 6 months of calendar year 2008. We then edited the data to remove claims from hospitals for clinical lab services, physical therapy services, and other services not paid using Medicare's Hospital Outpatient Prospective Payment System (OPPS). We also edited the VA purchased care claims data to eliminate physician services which would already be paid using Medicare's physician fee schedule, based on CPT code modifiers. We excluded claims with an extreme number of units or allowed amounts. We also excluded claims that were paid under contracts with hospitals or with certain managed care providers.

Under its current pricing policies, we found that in 2008, the VA paid an average of about $76 in hospital outpatient department and emergency room facility charges to non-VA facilities for each HOPD/ER service. Under Medicare OPPS pricing, the VA would pay an average of $51. This represents a cost reduction of approximately 33 percent. When extended to the universe of HOPD/ER charges for VA purchased care in 2008, we calculated an aggregate cost reduction of $62 million.

IMPACT OF MEDICARE PRICING ON NON-VA HOPD/ER FACILITY CHARGES

Payments under VA current method	Payments under Medicare OPPS pricing	Cost reduction	Cost reduction as a percentage of VA payments
$188.2M	$125.7M	$62.5M	33.2%

We also focused on the facility charges for the 15 procedures with the highest aggregate level of expenditures done in purchased care for VA beneficiaries. We found that these 15 codes accounted for almost one-third of the VA's payments for purchased care HOPD/ER charges in the first 6 months of CY 2009. Under Medicare OPPS

pricing for these 15 codes, 4 would receive increases of 10 percent or more and 4 would have decreases of 60 percent or more. Thus, using Medicare's pricing would result in some codes being paid more and some being paid less.

In examining the impact of OPPS among the top 15 codes, we found that two types of codes would have the greatest percentage reduction in their payments: Radiology codes and supplies (most routine supplies are bundled into the OPPS payments and are not paid separately). We analyzed the percentage reduction in payments for four broad types of HOPD services and found that payments for radiology would decrease by 42 percent and payments for the "other" category of services, which includes supplies, HCPCS codes, and drugs, would decrease by 85 percent. On the other hand, payments for medical services (including ER facility charges) would decrease by 5 percent and payment for surgeries would increase by almost 50 percent.

IMPACT OF OPPS BY TYPE OF SERVICE

Type of HOPD service	Percentage of current allowed amounts	Percentage change in allowed amounts under OPPS
Surgery	15	+47
Medical (includes ER)	18	−5
Radiology/Pathology	42	−42
Other (supplies, HCPCS, drugs)	25	−85
Total	100	−33

To project this analysis through FY15 (Table 1, below), we applied trend assumptions to the FY08 estimates. For both the Current Policy costs and the costs under Medicare pricing, we first applied assumed trends in the annual number of users for fee-basis care, which were supplied by the VA's National Fee Program Office. For long-run inflation per user, we applied separate trend assumptions to the Current Policy costs and the costs under Medicare pricing. For the Current Policy costs, we assumed long-run inflation per user of 7 percent per year. For the costs under Medicare pricing, we assumed long-run inflation per user of 2.5 percent per year.

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Table 1

($ in Millions)			FY08	FY09	FY10	FY11	FY12	FY13	FYY14	FY15
Assumed Annual Trends										
	Current Policy (Except for Hospice and Home Health, for which VA Already Uses Medicare Rates)									
		Fee Users		1.050	1.021	1.025	1.024	1.031	1.009	1.007
		Long-Run Inflation		1.070	1.070	1.070	1.070	1.070	1.070	1.070
		Total Trend		1.123	1.093	1.096	1.095	1.104	1.080	1.078
	Medicare Pricing									
		Fee Users		1.050	1.021	1.025	1.024	1.031	1.009	1.007
		Long-Run Inflation		1.025	1.025	1.025	1.025	1.025	1.025	1.025
		Total Trend		1.076	1.047	1.050	1.049	1.057	1.035	1.032
Clinical Lab										
	Current Policy		$71.4	$80.2	$87.6	$96.1	$105.3	$116.2	$125.5	$135.2
	Medicare Pricing		$18.1	$19.5	$20.4	$21.4	$22.5	$23.8	$24.6	$25.4
	Cost Impact		**-$53.3**	**-$60.7**	**-$67.2**	**-$74.7**	**-$82.8**	**-$92.4**	**-$100.9**	**-$109.8**
ESRD										
	Current Policy		$175.9	$197.6	$215.9	$236.7	$259.3	$286.2	$309.1	$333.0
	Medicare Pricing		$107.7	$115.9	$121.3	$127.4	$133.7	$141.3	$146.2	$150.9
	Cost Impact		**-$68.2**	**-$81.7**	**-$94.6**	**-$109.3**	**-$125.6**	**-$144.8**	**-$162.8**	**-$182.1**
ASC										
	Current Policy		$11.0	$12.4	$13.5	$14.8	$16.2	$17.9	$19.3	$20.8
	Medicare Pricing		$9.7	$10.4	$10.9	$11.5	$12.0	$12.7	$13.2	$13.6
	Cost Impact		**-$1.3**	**-$1.9**	**-$2.6**	**-$3.3**	**-$4.2**	**-$5.2**	**-$6.2**	**-$7.2**
HOPD (for services that would be subject to OPPS)										
	Current Policy		$167.6	$188.2	$205.7	$225.5	$247.0	$272.6	$294.4	$317.3
	Medicare Pricing		$116.8	$125.7	$131.6	$138.2	$145.0	$153.3	$158.6	$163.8
	Cost Impact		**-$50.7**	**-$62.5**	**-$74.1**	**-$87.3**	**-$102.0**	**-$119.3**	**-$135.8**	**-$153.5**
Total of All 4 Types of Services										
	Current Policy		$425.9	$478.3	$522.7	$573.1	$627.8	$692.8	$748.3	$806.3
	Medicare Pricing		$252.3	$271.5	$284.2	$298.5	$313.2	$331.2	$342.6	$353.7
	Cost Impact		**-$173.5**	**-$206.8**	**-$238.5**	**-$274.6**	**-$314.5**	**-$361.7**	**-$405.7**	**-$452.7**

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The resulting cost savings projections are presented in Table 2 below.

TABLE 2

FY	Estimated annual savings resulting from adoption of Medicare pricing standards for payment of out-patient services
2011	$274,600,000
2012	314,500,000
2013	361,700,000
2014	405,700,000
2015	452,700,000
Total	1,809,200,000

Reporting, Recordkeeping, and Other Compliance Requirements

This rule does not impose any reporting or recordkeeping requirements within the meaning of the Paperwork Reduction Act.

Identification of Duplicative, Overlapping, or Conflicting Federal Rules

There are no duplicative, overlapping, or conflicting Federal rules identified with this rule.

Congressional Review Act

Under the Congressional Review Act, a major rule may not take effect until at least 60 days after submission to Congress of a report regarding the rule. A major rule is one that would have an annual effect on the economy of $100 million or more or have certain other impacts. This final rule is a major rule under the Congressional Review Act.

Catalog of Federal Domestic Assistance Numbers

The Catalog of Federal Domestic Assistance numbers and titles are 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; and 64.011, Veterans Dental Care.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. John R. Gingrich, Chief of Staff, Department of Veterans Affairs, approved this document on December 3, 2010, for publication.

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, Government 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.

Dated: December 12, 2010.

Robert C. McFetridge,

Director, Regulation Policy and Management, Office of the General Counsel, Department of Veterans Affairs.

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

PART 17—MEDICAL

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

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

■ 2. Revise paragraph (a) introductory text of § 17.52 to read as follows:

§ 17.52 Hospital care and medical services in non-VA facilities.

(a) When VA facilities or other government facilities are not capable of furnishing economical hospital care or medical services because of geographic inaccessibility or are not capable of furnishing care or services required, VA may contract with non-VA facilities for care in accordance with the provisions of this section. When demand is only for infrequent use, individual authorizations may be used. Care in public or private facilities, however, subject to the provisions of §§ 17.53, 17.54, 17.55 and 17.56, will only be authorized, whether under a contract or an individual authorization, for—

* * * * *

■ 3. Revise § 17.56 to read as follows:

§ 17.56 VA payment for inpatient and outpatient health care professional services at non-departmental facilities and other medical charges associated with non-VA outpatient care.

(a) Except for health care professional services provided in the state of Alaska (see paragraph (b) of this section) and except for non-contractual payments for home health services and hospice care, VA will determine the amounts paid under §§ 17.52 or 17.120 for health care professional services, and all other medical services associated with non-VA outpatient care, using the applicable method in this section:

(1) If a specific amount has been negotiated with a specific provider, VA will pay that amount.

(2) If an amount has not been negotiated under paragraph (a)(1) of this section, VA will pay the lowest of the following amounts:

(i) The applicable Medicare fee schedule or prospective payment system amount ("Medicare rate") for the period in which the service was provided (without any changes based on the subsequent development of information under Medicare authorities), subject to the following:

(A) In the event of a Medicare waiver, the payment amount will be calculated in accordance with such waiver.

(B) In the absence of a Medicare rate or Medicare waiver, payment will be the VA Fee Schedule amount for the period in which the service was provided. The VA Fee Schedule amount is determined by the authorizing VA medical facility, which ranks all billings (if the facility has had at least eight billings) from non-VA facilities under the corresponding procedure code during the previous fiscal year, with billings ranked from the highest to the lowest. The VA Fee Schedule amount is the charge falling at the 75th percentile. If the authorizing facility has not had at least eight such billings, then this paragraph does not apply.

(ii) The amount negotiated by a repricing agent if the provider is participating within the repricing agent's network and VA has a contract with that repricing agent. For the purposes of this section, *repricing agent* means a contractor that seeks to connect VA with discounted rates from non-VA providers as a result of existing contracts that the non-VA provider may have within the commercial health care industry.

(iii) The amount that the provider bills the general public for the same service.

(b) For physician and non-physician professional services rendered in Alaska, VA will pay for services in accordance with a fee schedule that uses the Health Insurance Portability and Accountability Act mandated national standard coding sets. VA will pay a specific amount for each service for which there is a corresponding code. Under the VA Alaska Fee Schedule, the amount paid in Alaska for each code will be 90 percent of the average amount VA actually paid in Alaska for the same services in Fiscal Year (FY) 2003. For services that VA provided less than eight times in Alaska in FY 2003, for services represented by codes established after FY 2003, and for unit-based codes prior to FY 2004, VA will take the Centers for Medicare and Medicaid Services' rate for each code and multiply it times the average percentage paid by VA in Alaska for Centers for Medicare and Medicaid Services-like codes. VA will increase the amounts on the VA Alaska Fee Schedule annually in accordance with the published national Medicare Economic Index (MEI). For those years where the annual average is a negative percentage, the fee schedule will remain the same as the previous year. Payment for non-VA health care professional services in Alaska shall be the lesser of the amount billed or the amount calculated under this subpart.

(c) Payments made by VA to a non-VA facility or provider under this section shall be considered payment in full. Accordingly, the facility or provider or agent for the facility or provider may not impose any additional charge for any services for which payment is made by VA.

(d) In a case where a veteran has paid for emergency treatment for which VA may reimburse the veteran under § 17.120, VA will reimburse the amount that the veteran actually paid. Any amounts due to the provider but unpaid by the veteran will be reimbursed to the provider under paragraphs (a) and (b) of this section.

(Authority: 38 U.S.C. 1703, 1728)

[FR Doc. 2010–31629 Filed 12–16–10; 8:45 am]

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POSTAL SERVICE

39 CFR Part 232

Conduct on Postal Property

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: The U.S. Postal Service is updating its regulations concerning Conduct on Postal Property (COPP) to correct or eliminate outdated citations, obviate the need for continuous updates of such citations by harmonizing the regulations with federal law, and make certain other minor, editorial revisions.

DATES: *Effective date:* December 17, 2010.

FOR FURTHER INFORMATION CONTACT: Christy Noel, Attorney, U.S. Postal Service, 202–268–3484.

SUPPLEMENTARY INFORMATION: The current rules governing Conduct on Postal Property contain a number of outdated or confusing references to non-postal statutes, and in some cases do not