

amend 29 CFR chapter XIV part 1625 as follows:

PART 1625—AGE DISCRIMINATION IN EMPLOYMENT ACT

1. The authority citation for part 1625 continues to read as follows:

Authority: 81 Stat. 602; 29 U.S.C. 621; 5 U.S.C. 301; Secretary's Order No. 10–68; Secretary's Order No. 11–68; Sec. 9, 81 Stat. 605; 29 U.S.C. 628; sec. 12, 29 U.S.C. 631, Pub. L. 99–592, 100 Stat. 3342; sec. 2, Reorg. Plan No. 1 of 1978, 43 FR 19807.

Subpart A—Interpretations

2. Revise paragraph (b) of § 1625.7 to read as follows:

§ 1625.7 Differentiations based on reasonable factors other than age.

* * * * *

(b) Whether a differentiation is based on reasonable factors other than age (“RFOA”) must be decided on the basis of all the particular facts and circumstances surrounding each individual situation.

(1) *Reasonable.* A reasonable factor is one that is objectively reasonable when viewed from the position of a reasonable employer (i.e., a prudent employer mindful of its responsibilities under the ADEA) under like circumstances. To establish the RFOA defense, an employer must show that the employment practice was both reasonably designed to further or achieve a legitimate business purpose and administered in a way that reasonably achieves that purpose in light of the particular facts and circumstances that were known, or should have been known, to the employer. Factors relevant to determining whether an employment practice is reasonable include but are not limited to, the following:

(i) Whether the employment practice and the manner of its implementation are common business practices;

(ii) The extent to which the factor is related to the employer's stated business goal;

(iii) The extent to which the employer took steps to define the factor accurately and to apply the factor fairly and accurately (e.g., training, guidance, instruction of managers);

(iv) The extent to which the employer took steps to assess the adverse impact of its employment practice on older workers;

(v) The severity of the harm to individuals within the protected age group, in terms of both the degree of injury and the numbers of persons adversely affected, and the extent to which the employer took preventive or

corrective steps to minimize the severity of the harm, in light of the burden of undertaking such steps; and

(vi) Whether other options were available and the reasons the employer selected the option it did.¹

(2) *Factors Other Than Age.* When an employment practice has a significant disparate impact on older individuals, the RFOA defense applies only if the practice is not based on age. In the typical disparate impact case, the practice is based on an objective non-age factor and the only question is whether the practice is reasonable. When disparate impact results from giving supervisors unchecked discretion to engage in subjective decision making, however, the impact may, in fact, be based on age because the supervisors to whom decision making was delegated may have acted on the bases of conscious or unconscious age-based stereotypes. Factors relevant to determining whether a factor is “other than age” include, but are not limited to, the following:

(i) The extent to which the employer gave supervisors unchecked discretion to assess employees subjectively;

(ii) The extent to which supervisors were asked to evaluate employees based on factors known to be subject to age-based stereotypes; and

(iii) The extent to which supervisors were given guidance or training about how to apply the factors and avoid discrimination.

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¹ This does not mean that an employer must adopt an employment practice that has the least severe impact on members of the protected age group. “Unlike the business necessity test, which asks whether there are other ways for the employer to achieve its goals that do not result in a disparate impact on a protected class, the reasonableness inquiry includes no such requirement.” *Smith v. City of Jackson*, 544 U.S. 228, 243 (2005). Instead, this simply means that the availability of other options is one of the factors relevant to whether the practice was a reasonable one. “If the actor can advance or protect his interest as adequately by other conduct which involves less risk of harm to others, the risk contained in his conduct is clearly unreasonable.” Restatement (Second) of Torts 292, cmt. c (1965).

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: Proposed rule.

SUMMARY: This document proposes to update 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.

DATES: Comments must be received on or before April 19, 2010.

ADDRESSES: Written comments may be submitted by email through <http://www.regulations.gov>; by mail or hand-delivery to Director, Regulations Management (00REG1), Department of Veterans Affairs, 810 Vermont Ave., NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. Comments should indicate that they are submitted in response to “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.” Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8 a.m. and 4:30 p.m. Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Joseph C. Enderle, Jr., National Fee Program Manager, Department of Veterans Affairs, P.O. Box 469066, Denver, CO 80246–9066, telephone (303) 370–5088. (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 shall 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 conditions aggravating a service-connected disability. 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 be 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 non-VA physician and other health care 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 vast 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 schedules. We propose to broaden § 17.56 to apply a new payment methodology to all non-VA inpatient and outpatient health care professional services and other outpatient services. Such charges would include ancillary and facility costs such as those that are reimbursed using the following Medicare schedules:

Ambulatory Surgical Center Payment, Clinical Laboratory Fee Schedule, Home Health Prospective Payment System (“PPS”), Hospice, Hospital Outpatient PPS, and End Stage Renal Disease composite rate payment method. In the absence of an amount negotiated between VA and the provider under the Federal Acquisition Regulation (“FAR”), this new methodology will allow VA to pay the lesser of an amount negotiated under the VA Acquisition Regulation (“VAAR”), the applicable Medicare or VA Fee schedule rate, and the billed charge.

VA OIG Report 05–03037–107 (2006) concluded that clarification of VA’s regulatory authority for payment of outpatient facility charges is necessary to ensure consistent, predictable medical costs and control expenditures. This audit recommended that VA adopt Medicare fee schedules via specific regulatory action. VA subsequently determined that in the absence of a contract it had authority to pay facility charges and similar costs utilizing Medicare rates as its payment methodology without regulatory change. As a result, in early 2009, VA utilized Medicare schedules for a brief period of time to pay for certain institutional services. In response to an expressed concern received from a health care organization, VA determined that regulatory action was the preferred method of implementing Medicare schedules. We believe that using the Medicare schedules will clearly help VA contain costs, as explained in greater detail later in this notice. It is in the interest of the American public that these methodologies be adopted in order to help contain costs. We recognize that potential cost-savings realized by VA as a result of this proposed rule will economically impact the health care community. Historically, other Federal payers have utilized a phased-in approach for implementation of changes resulting in an economic transfer action upon the health care community. We solicit comments from the health care industry as to how VA may best implement such a transition.

The current § 17.56 states that “[n]otwithstanding other provisions of this section, VA, for physician services covered by this section, will pay the lesser of the amount determined under paragraphs (a) through (e) of this section or the amount negotiated with the physician or the physician’s agent.” There are three basic types of negotiated contracts VA uses to pay for purchased health care: (1) Contracting under 48 CFR, (2) negotiated contracts under 48 CFR Chapter 8, and (3) negotiated contracts using a repricing agent. We

propose 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. Proposed paragraph (a) would require that the costs of the listed services be paid in accordance with a preferential hierarchy set forth in paragraphs (a)(1) and (a)(2). The proposed rule would give preference to “[t]he amount negotiated by VA and the provider under Federal Acquisition Regulation (FAR), 48 CFR Chapter 1.”

However, proposed § 17.56(a)(1) does not fully reflect VA’s existing statutory and regulatory authority to negotiate rates through the contracting authority in 38 U.S.C. 1703 and the regulatory procedures set forth in 48 CFR Chapter 8, or to apply rates negotiated by a repricing agent. Accordingly, in proposed paragraph (a)(2)(i) and (a)(2)(ii), we added a clarifying amendment to specify that negotiating such agreements is the preferred method for determining payment amounts for all non-VA physician and other health care professional services only if such amount is lesser than would be payable under the applicable Medicare or VA Fee Schedule rate and billed charge.

Accordingly, proposed paragraph (a)(2) would provide the second payment methodology, which would be the lesser of the amounts described in paragraphs (a)(2)(i), (ii), (iii), or (iv). Proposed paragraph (a)(2)(i) is based upon the authority to enter into negotiated contracts under 48 CFR 801.670–3. Proposed paragraph (a)(2)(ii) is based on current § 17.56(f), which in part currently permits VA to pay physicians the amount that they have negotiated with an agent. The proposed paragraph would clarify the current rule. We would use the word “provider” where current paragraph (f) uses “physician” because we propose to broaden this regulation to reach “other medical charges associated with non-VA outpatient care.” We would also use the term “repricing agent” instead of “physician’s agent” for the same reason.

Paragraph (a)(2)(iii)(A) and (B) would describe the payment methodology that applies where there has been no negotiated amount. In paragraph (a)(2)(iii)(A), we would adopt Medicare’s “applicable fee schedule or prospective payment system payment amount.” As explained above regarding proposed § 17.56(a), this regulation would apply the Medicare rates to more than simply physician professional services, as is done in the current rule.

Under current law, the Federal Government may waive Medicare

payment rules and allow alternative payment methods. At this time, such a waiver has been granted only to hospitals in the state of Maryland. In our view, the Medicare methodology implemented in current § 17.56 and that we propose to expand in this rulemaking includes alternative payment methods authorized under a Medicare waiver. We propose to clarify in proposed paragraph (a)(2)(iii)(A) that absent a lesser charge under proposed paragraphs (a)(2)(i), (ii) or (iv), payment will be made in accordance with the terms of any alternative methodology authorized by a Medicare waiver or as otherwise prescribed in paragraph (a)(2)(iii)(A).

Paragraph (a)(2)(iii)(A) would not include the exception in current § 17.56(a) for payments for “anesthesia services.” This exception is no longer required because Medicare includes payment for anesthesia in its fee schedules and prospective payment systems. The current regulation also describes in detail the payment formula for physician and non-physician professional services, which is already included in the Medicare fee schedule that VA would adopt under this rule. There is no reason to repeat it in the proposed regulation.

We also note that this rule would not authorize additional payments or any payment adjustments greater than the amount specified in the published Medicare fee schedule and prospective payment system, such as end-of-year settlements or other periodic adjustments made by Medicare as a result of cost reporting. Such adjustments allow for additional payments or recovery of payment on the basis of actual cost as reported by Medicare participating providers. The payments determined by cost reporting for hospital outpatient services include transitional pass-through payments, bad debts, and costs of direct medical education. Unlike Medicare, VA is a direct supporter of medical education through its residency, internship, and research affiliations with educational institutions. Furthermore, a treating facility incurs no risk of bad debt accumulation as a result of referral of veterans for treatment, as VA pays 100 percent of the determined allowable amount. VA does not have systems in place to obtain the data necessary to make such adjustments, and we believe it would not be cost-effective for us to develop such systems because of the relatively small numbers of veterans affected. In contrast, Medicare has a larger program that reaches a significantly larger group of people than the number of veterans whose non-VA

care is paid for under §§ 17.52 and 17.120. For these reasons VA proposes not to make settlement or adjustment payments.

Proposed paragraph (a)(2)(iii)(B) would apply “[i]n the absence of a Medicare rate.” In such cases, we would apply the formula in current § 17.56(c), which we would restate in paragraph (a)(2)(iii)(B).

Under paragraph (a)(2)(iv), we would pay “[t]he amount the provider bills the general public for the same service.” If the provider is willing to accept payment from the general public of an amount that is less than the other amounts set forth in paragraphs (a)(2)(i), (ii), or (iii), there would be no reasonable justification in our view for charging the government a greater amount for the same services.

Proposed paragraph (b) would repeat the exception in the current § 17.56(d) for services provided in the state of Alaska, without substantive change.

Paragraph (c) would bar providers or their agents from imposing any additional charges to those authorized for payment under this section. This is based on current § 17.56(e) and is substantively identical.

Proposed paragraph (d) would implement recent revisions to 38 U.S.C. 1728(a) that require VA to “reimburse [certain] veterans eligible for hospital care or medical services under [38 U.S.C. chapter 17] for the customary and usual charges of emergency treatment (including travel and incidental expenses under the terms and conditions set forth in [38 U.S.C. 111]) for which such veterans have made payment, from sources other than [VA].” We interpret this provision to authorize VA to reimburse the veteran for all of his or her out-of-pocket payments relating to the emergency treatment; however, we do not interpret this provision to bar the application of the sound, cost-savings principles used to reimburse providers in paragraphs (a) and (b). Therefore, under this rule, we would reimburse the veteran for out-of-pocket payments and, if there is any remaining balance due to the provider, VA would reimburse the provider using the principles set forth in proposed paragraphs (a) and (b).

Finally, as a result of this proposed rule making, it came to our attention that 38 CFR 17.52(a) contains a typographical error. 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 propose that the reference in § 17.52(a) to the “provisions of § 17.53 through f” should be amended to the “provisions of §§ 17.53, 17.54, 17.55 and 17.56.”

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 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 proposed 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.

Regulatory Impact Analysis

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 hospital care and inpatient and outpatient physician services. Moreover, two separate audits by VA’s Office of Inspector General concluded that clarification of VA’s regulatory authority for 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 expenditures. Thus, we believe that adoption of this rate is important to both VA and the general public.

Impact

An estimate of the number of small entities potentially affected by this rule may be found in the Regulatory Flexibility Act section below. The following “Benefit-Cost Analysis” discussion provides a high level overview concerning the economic impact of this proposed rule. We seek any information or comment on these and other issues.

Benefits-Cost Analysis

End Stage Renal Disease (ESRD)

To estimate the potential savings to be realized with the adoption of Medicare pricing, we first identified outpatient dialysis services provided to veterans in non-VA facilities in the first six months of calendar year 2008. We focused on a subset of dialysis procedure and injectable drug codes that together accounted for the vast bulk of outpatient dialysis facility charges for care purchased by 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 injectable drugs are normally administered as multiple units of service. We also excluded claims that VA reimbursed 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 separately payable injectable drugs). Medicare’s national average composite rate (approximately \$157 per dialysis session) was used in this analysis. This rate was adjusted using Medicare’s geographic wage index adjustment for ESRD dialysis facility charges. For the injectable drug claims Medicare prices were used. 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 negotiated a lower rate than the Medicare rate).

Cost reductions for the dialysis procedures ranged from 21–35 percent for the three most common dialysis codes and the savings on injectable drugs ranged from 48–69 percent for the three most common codes. By utilizing Medicare pricing we estimate that VA’s outpatient dialysis facility expenditures will decrease by 39 percent.

Clinical Lab Services

Similarly, we first identified all clinical lab services provided through VA purchased care to veterans in the first six months of calendar year 2008. We then edited the data to remove outliers (claims paid under \$1 or over \$500). We also eliminated a very small number of claims that we 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 physician

claims, clinical labs at Maryland hospitals, and critical access hospitals because they are not subject to the Medicare lab fee schedule. 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 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, the VA would pay an average of \$11.47 for these claims. This represents a cost reduction of approximately 75 percent.

We performed further analysis of the 15 clinical lab codes with the highest VA purchased care volumes. We found that these 15 clinical lab codes accounted for about one-half of the VA’s payments for clinical lab services in the first six months of CY08. 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.

Home Health Care/Hospice

The estimated impact of using Medicare’s home health care and hospice payment methodologies is zero. We estimate no impact because VA currently utilizes these payment methodologies for reimbursement of such non-VA care.

Percent of Veterans Utilizing VA Health Care System

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
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	4,940,212	1.6

Accounting Statement

It is anticipated that adoption of Medicare pricing standards for outpatient care would result in significant cost savings; however, the amount of savings will vary depending on current VA payment methodology and utilization rates. Under current § 17.56, VA utilizes Medicare's participating physician fee schedule for the payment of physician and

professional services for both inpatient and outpatient care; therefore no savings would be realized for the portion of non-VA outpatient expenditures for services paid under that pricing standard.

The following assumptions were used to arrive at a projected savings estimate:

- Outpatient disbursements for future years are based on total expenditures for non-VA outpatient services during 2006, 2007 and 2008, the number of

veteran users, and an anticipated inflation rate.

- The number of veteran users for outpatient purchased care services was estimated at 8 percent of the number of enrolled veterans for future years.
- The anticipated inflation rate used in the estimate is 3.5 percent for 2008–2011, 3.7 percent for 2012, and 3.8 percent for all subsequent years.

- Outpatient disbursements made in FY 2008 were used to identify disbursements for specific categories of outpatient services, such as: clinical laboratory, dialysis, ambulatory surgical center, home health, hospice, etc.
- Savings were estimated by comparing current VA payment methodology for sample codes within each category with the Medicare's pricing standards for the same codes to determine an estimated percentage of savings.
- The percentage of savings for each category was then used to calculate the estimated savings if Medicare pricing standards were adopted.
 - Savings for dialysis services using Medicare pricing standards are estimated at 39 percent.
 - Savings for laboratory services using Medicare pricing standards are estimated at 75 percent.
 - Savings for Ambulatory Surgery Center services using Medicare pricing standards are estimated at 11 percent.
- No savings were anticipated for either home health care or hospice services, as these services are paid by VA utilizing Medicare LUPA rates.
- Facility charges were estimated for all other outpatient service expenditures. It is anticipated that a cost savings of 25 percent will be realized in this category.

Fiscal year	Estimated annual savings resulting from adoption of medicare pricing standards for payment of outpatient services
2011	\$251,800,000
2012	280,400,000
2013	314,200,000
2014	344,100,000
2015	375,600,000
Estimated Total Savings	1,566,100,000

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.

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 proposed rule is a major

rule under the Congressional Review Act.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) 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 Small Business Administration (SBA) definition of a small business, as codified in 13 CFR 121.201. Therefore, the Secretary has determined that this proposed rule would have a significant impact on a substantial number of small entities.

An Initial Regulatory Flexibility Analysis (IRFA) has been prepared and submitted to the Chief Counsel for Advocacy of the Small Business Administration in accordance with 5 U.S.C. 603. Interested parties are invited to submit comments on VA's regulatory flexibility analysis. The analysis is as follows:

Description of the Reasons Why Action by the Agency Is Being Considered

This document proposes to update 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. Moreover, two separate audits by VA's Office of Inspector General concluded that clarification of VA's regulatory authority for 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.

Succinct Statement of the Objectives of, and Legal Basis for, the Proposed Rule

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. 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.

Description of, and, Where Feasible, Estimate of the Number of Small Entities To Which the Proposed Rule Will Apply

Kidney Dialysis Centers (North American Industry Classification System (NAICIS) 621492)

Payments excluded from this analysis include services purchased by competitive contracting, services purchased in foreign countries, and emergency care ESRD services authorized under 38 U.S.C. 1725. Lesser payment rates negotiated between VA and the non-VA provider are included, as VA is unable to identify such payments in its centralized payment files. VA has authority under 38 CFR 17.56 to negotiate a lesser payment amount with non-VA providers for services purchased on an individual basis. We acknowledge that inclusion of negotiated payment rate data overstates the financial impact upon small businesses.

VA payment information is primarily maintained by the payee's federal tax identification number (TIN). VA assigns a two character suffix to the base nine-digit TIN to distinguish multiple components of an entity; however, the payment files are indexed by the vendor remit-to-addresses rather than the place of service. For this reason we conducted a comprehensive geographical analysis of payments based upon the address of the payee.

Medicare utilizes their ESRD prospective payment pricer for the payment for ESRD treatment. Dialysis treatments are performed mostly at dialysis centers and paid by Medicare under the method 1 of the ESRD pricer. Medicare may pay home dialysis treatments using a second method of determining pricing, which is known as method 2. When VA authorizes dialysis treatment and negotiates a payment rate based upon Medicare methodology it pays for such dialysis treatments under method 1. The percentage of vendors receiving VA payments for all ESRD related treatment totaling less than \$50,000 was 82 percent; the percentage of vendors receiving payments totaling

A total of 1,888 health care providers furnished care in an end stage renal disease treatment facility at VA expense. Approximately 90 percent of the total annual payments received by these providers was less than \$100,000. All of the providers with earnings equal to or

greater than \$100,000 were dialysis treatment centers, representing 9.5 percent of the total providers paid. There were approximately 484 dialysis centers in 2002 and approximately 85 percent of these dialysis centers (NAICS 621492) were classified as small businesses earning less than \$10 million per year (<http://www.sba.gov/advo/>

The following table illustrates the location and amount of annual VA payments in increments of \$50,000 to these 180 dialysis treatment centers.

[Sorted by state in increments of \$50,000]

VA payment range	\$100,000 \$150,000	\$150,000 \$200,000	\$200,000 \$250,000	\$250,000 \$300,000	\$300,000 \$350,000	\$350,000 \$400,000	\$400,000 \$450,000	\$450,000 \$500,000
State:								
AL	1							
AR						1		
AZ	1	1	2	1	1		1	
CA	5	1	1					
CO			1					
FL	1	3						
GA	6	5	3	4	1	1	1	1
HI								
IL	3	2	2		1		2	
IN		1						
KS	1		1				1	
KY	2			1				
LA			1					
MA	1	1	2		1			
MD		3			1			
MI	3			1				
MO	1							
NC	5	1	1	1				
NH		1						
NM					1			
NY	3							
OH		3		1				
PA	5	5	1				1	1
SC	1							
TN	4	1	2	1	1	1	1	
TX	3	2			2	1		
WA	3							
WI	1			2				
WV				1				
Total	50	30	17	13	9	4	7	2
Percent of Total	2.6	1.6	0.9	0.7	0.5	0.2	0.4	0.1

[Sorted by state in increments of \$50,000]

[illegible]

AMOUNT OF VA PAYMENTS TO VENDORS FOR DIALYSIS TREATMENT IN ESRD FACILITIES—Continued
 [Sorted by state in increments of \$50,000]

VA payment range	\$500,000 \$550,000	\$550,000 \$600,000	\$600,000 \$650,000	\$650,000 \$700,000	\$700,000 \$750,000	\$750,000 \$800,000	\$800,000 \$850,000	\$850,000 \$900,000	\$900,000 \$950,000	\$950,000+
NM
NY
OH
PA	1	1	2	1	1	4
SC
TN	1	2	1	1	2
TX	1	1
WA	1
WI
WV
Total	5	5	1	4	4	2	2	0	4	20
Percent of Total	0.3	0.3	0.1	0.2	0.2	0.1	0.1	0.0	0.2	1.1

During fiscal year 2008, approximately 10,500 veterans received dialysis treatment at non-VA facilities at VA expense, which represents 2.8 percent of all persons receiving dialysis in the United States. One major dialysis provider characterized government programs, other than Medicare and Medicaid programs, as comprising 2 percent of their annual revenues for calendar year ending December 31, 2008, as stated on their annual Securities Exchange Commission form 10-K submission. We consider these reported numbers as reflective of VA workload throughout the dialysis treatment industry and conclude that VA patient workload in dialysis centers does not represent a substantial source of income for these businesses.

Clinical Diagnostic Laboratory (Medical Laboratories NAICS 621511)

Medicare utilizes the Clinical Diagnostic Laboratory fee schedule to determine the payment amount for laboratory tests. Both VA and Medicare use the Physician Fee Schedule to pay professional interpretation and reporting fees associated with laboratory tests. Under this proposal, VA would use the Medicare Clinical Diagnostic Laboratory fee schedule to pay for laboratory tests purchased from non-VA providers. In FY 2008, VA paid 8,283 unique vendors for laboratory services purchased from health care facilities and providers. VA annual payments for these services totaled less than \$50,000 for 98 percent of the vendors paid, 99.2 percent of vendors received less than \$100,000, and 99.5 percent of vendors were paid less than \$150,000 per year. A total of 13 vendors were paid an annual sum greater than \$300,000. VA estimates that payment for laboratory services utilizing the Medicare Clinical Laboratory Diagnostic fee schedule will reduce the amount of payments by approximately 75 percent. Due to the

current level of workload and VA expenditures per non-VA facility we do not consider adoption of Medicare reimbursement rates for laboratory services to have a major financial impact upon individual entities.

Home Health Care Services (NAICS 621610)

VA purchases home health care and hospice care in accordance with 38 U.S.C. 7120(c). These services are paid for via contracts, basic coordinated agreements, provider agreements and/or other negotiated agreements. Currently, Medicare Low Utilization Payment Adjustment (LUPA) rates are used by VA to determine acceptable rates upon which to base contracts and agreements for such non-VA care purchases. In addition to the LUPA rates, VA takes into consideration the need for and provision of services not otherwise included in the Medicare PPS. Such additional services will continue to be paid for by VA under the proposed regulatory changes. This proposed rule will simply codify the practices currently in place, and no significant financial impact on non-VA providers is anticipated.

General Medical & Surgical Hospitals/ Freestanding Ambulatory Surgical & Emergency Centers (NAICS 622110/ 621493)

We propose to adopt the Medicare ASC and Hospital OPPS payment methodology for payment of invasive and non-invasive procedures and treatment in an outpatient hospital setting or freestanding surgical center that VA authorizes under 38 U.S.C. 1703 and 1728. VA currently pays for such facility charges utilizing its 75th percentile methodology. VA is unable to accurately project potential cost savings realized from utilizing Medicare Hospital OPPS payment methodology. During Fiscal Year 2008, less than one-

half of one percent of all facilities paid that furnished non-VA care in emergency departments received payments greater than \$100,000 per year. Additionally, the majority of payments for care rendered in ambulatory surgical centers during FY 2008 was below \$50,000 per facility (95.4 percent; 99.2 percent were paid less than \$150,000 per year). We project that adopting Medicare ASC methodology will result in a reduction of approximately 11 percent and we estimate a reduction of 25 percent for hospital outpatient expenditures.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule, Including an Estimate of the Classes of Small Entities Which Will Be Subject to the Requirement and the Type of Professional Skills Necessary for Preparation of the Report or Record

This rulemaking will impose no new reporting or recordkeeping requirements on large or small entities.

Identification, to the Extent Practicable, of All Relevant Federal Rules Which May Duplicate, Overlap, or Conflict With the Proposed Rule

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

Description of Any Significant Alternatives to the Proposed Rule Which Would Accomplish the Stated Objectives of Applicable Statutes and Which Would Minimize Any Significant Economic Impact of the Proposed Rule on Small Entities

We believe adoption of Medicare payment schedules would standardize VA reimbursement for the purchase of non-VA health care services as suggested by previous OIG audits. For reasons discussed above in the cost-benefits-analysis section of the

Regulatory Impact Analysis, we do not believe there are any reasonable alternatives to our adoption of all current and future Medicare payment schedules and prospective payment systems. Historically, other Federal payers have transitioned changes to payment methodology over a period of time to lessen the potential financial impact upon the health care community. We believe an immediate adoption of Medicare rates is reasonable because most health care providers are accustomed to Medicare rates, and there is low VA market penetration in the non-VA health care community. Furthermore, we believe the cost-savings realized as a result of adopting Medicare rates would be beneficial to the veteran population. However, we are sensitive to the needs of the health care community and we welcome any comments regarding plausible alternatives for implementation, including a phased-in approach.

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 proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

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

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 home care, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Approved: September 15, 2009.

John R. Gingrich,

Chief of Staff, Department of Veterans Affairs.

For the reasons set forth in the preamble, VA proposes to amend 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), VA will determine the amounts paid under §§ 17.52 or 17.120 for inpatient and outpatient health care professional services, and all other medical services associated with non-VA outpatient care, using the applicable method in this section:

(1) The amount negotiated by VA and the provider under Federal Acquisition Regulation (FAR), 48 CFR Chapter 1.

(2) If an amount has not been negotiated under paragraph (a)(1), VA will use the lesser of the following:

(i) The amount negotiated by VA and the provider under Department of Veterans Affairs Acquisition Regulation (VAAR), 48 CFR Chapter 8;

(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; or

(iii) Either:

(A) The applicable Medicare fee schedule or prospective payment system payment 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). In the event of a Medicare waiver, payment will be made in accordance with such waiver; or

(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; or

(iv) The amount 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 provider or facility 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. 2010-3042 Filed 2-17-10; 8:45 am]

BILLING CODE 8320-01-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 600 and 697

RIN 0648-XT83

Atlantic Coastal Fisheries Cooperative Management Act Provisions; Application for Exempted Fishing Permits (EFPs)

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notification of a request for an EFP; request for comments.

SUMMARY: This EFP application, submitted by the Pemaquid Fishermen's Cooperative Association (PFC), is intended to assist NMFS and the Atlantic Large Whale Take Reduction Team (ALWTRT) in their efforts to address the identified entanglement threat of vertical lines in fixed gear fisheries to Atlantic large whale populations. The EFP application is for testing of fixed fishing gear with no vertical lines on the northern edge of Jeffrey's Ledge in the Gulf of Maine.

The Assistant Regional Administrator for Sustainable Fisheries, Northeast Region, NMFS (Assistant Regional Administrator), has made a preliminary determination that the subject EFP application contains all the required information and warrants further consideration and that the activities authorized under the EFP would be consistent with the goals and objectives of federal management of the American lobster (lobster) resource. However, further review and consultation may be necessary before a final determination is made to issue an EFP. NMFS announces that the Assistant Regional Administrator proposes to issue an EFP

and, therefore, invites comments on the issuance of this EFP.

DATES: Comments must be received on or before March 5, 2010.

ADDRESSES: Written comments should be sent to Patricia A. Kurkul, Regional Administrator, NMFS, Northeast Regional Office, 55 Great Republic Drive, Gloucester, MA 01930-2298. Mark the outside of the envelope "Comments - Lobster EFP Proposal." Comments also may be sent via facsimile (fax) to 978-281-9117. Comments may also be submitted by e-mail to Al lobster@noaa.gov. Include in the subject line of the e-mail the following document identifier: "Comments - Lobster EFP Proposal."

FOR FURTHER INFORMATION CONTACT: Sarah Towne, Research Associate, (978) 675-2162, fax (978) 281-9117.

SUPPLEMENTARY INFORMATION:

Background

The regulations that govern exempted fishing, at § 600.745(b) and § 697.22, allow the Regional Administrator to authorize for limited testing, public display, data collection, exploration, health and safety, environmental clean-up, and/or hazardous removal purposes, and the targeting or incidental harvest of managed species that would otherwise be prohibited. An EFP to authorize such activity may be issued, provided there is adequate opportunity for the public to comment on the EFP application, the conservation goals and objectives of federal management of the lobster resource are not compromised, and issuance of the EFP is beneficial to the management of the species.

The lobster fishery is one of the most valuable fisheries in the northeastern United States. In 2008, approximately 82 million lbs (37,120 mt) of lobster were landed, with an ex-vessel value of approximately \$306 million. Under the Atlantic States Marine Fisheries Commission's interstate management process, lobsters are managed in state waters under Amendment 3 to the American Lobster Interstate Fishery Management Plan (Amendment 3). In federal waters of the Exclusive Economic Zone (EEZ), lobsters are managed under federal regulations at 50 CFR part 697.

The ALWTRP is a program to reduce the risk of serious injury or death of large whales due to incidental entanglement in U.S. commercial fishing gear. The plan is required by the Marine Mammal Protection Act (MMPA), and has been implemented by NMFS. The ALWTRP evolves as NMFS and the ALWTRT learn more about why whales become entangled and how

fishing practices might be modified to reduce the risk of entanglement.

Proposed EFP

The EFP application requests exemptions from regulations in order to conduct gear research on the northern edge of Jeffrey's Ledge in the Gulf of Maine to study fixed lobster fishing gear without vertical lines that could reduce or diminish whale entanglement. One contracted commercial fisherman would fish 140 traditional wire lobster traps with no vertical lines (experimental) and 140 traditional wire lobster traps with vertical lines (control), each set in multiple trawl configurations, rigging no fewer than 7 trawls with 20 traps each. Both the experimental and control group trawls would be hauled 30 times each during the fishing season, totaling no fewer than 420 hauls. The EFP application proposes the collection of statistical and scientific information as part of the project. Investigators would complete a NMFS-approved data sheet on each trip, collecting data on weather and sea conditions, position of gear, bottom type, water depth and temperature, duration of hauling time, set time, trap loss, configuration changes, hauling procedure modifications, catch, price per pound, and gear conflicts.

Trawls would be tested on different bottom types, and the grappling hook gear used to retrieve the lineless trawls would be specific to that bottom type. Although the grappling hooks might adversely impact benthic habitats, their limited use for the proposed activity would not constitute a threat that is significantly greater than the one associated with the impact of the traps themselves, or of the other lobster traps that are already being fished in the proposed project location. Therefore there would be no anticipated adverse effects on protected resources or habitat as a result of this work.

This project would not involve the authorization of any additional lobster trap gear. To allow for experimentation with traps without vertical lines, the EFP would provide exemptions from the vertical line and buoy regulations at § 697.21(b)(2). All traps fished by the participating vessel would comply with all other applicable lobster regulations specified at 50 CFR part 697. There would not be observers or researchers onboard the participating vessel.

Authority: 16 U.S.C. 1801 *et seq.*