Dated: July 11, 2005.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 05–14630 Filed 7–25–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 549

[BOP–1111–F]

RIN 1120–AB11

Inmate Fees for Health Care Services

AGENCY: Bureau of Prisons, Justice.

ACTION: Final rule.

SUMMARY: The Bureau of Prisons (Bureau) finalizes rules describing procedures we will follow for charging inmates fees for certain kinds of health services, as required under the Federal Prisoner Health Care Copayment Act of 2000 (Pub. L. 106–294, October 12, 2000, 114 Stat 1038, codified at 18 U.S.C. 4048).

DATES: This rule is effective on October 3, 2005. We will not implement the provisions of this rule until 30 days after we have given notice of these rules to inmates in our custody, as required by 18 U.S.C. 4048(i).

ADDRESSES: Rules Unit, Office of General Counsel, Bureau of Prisons, 320 First Street, NW., Washington, DC 20534.

FOR FURTHER INFORMATION CONTACT: Sarah Qureshi, Office of General Counsel, Bureau of Prisons, phone (202) 307–2105.

SUPPLEMENTARY INFORMATION: Under the Federal Prisoner Health Care Copayment Act of 2000 (Pub. L. 106–294, October 12, 2000, 114 Stat 1038, codified at 18 U.S.C. 4048) (Act), the Bureau of Prisons (Bureau) may assess and collect a fee for health care services provided in connection with certain kinds of inmate health care visits. In this document, we finalize our proposed rule which was published on October 10, 2002 (67 FR 63059) describing procedures we will follow for charging inmates health service fees for certain kinds of health care services.

Response to Comments

We received 42 comments on our proposed rules. One commenter supported the rule. Eight of the comments were copies of one form letter, and another thirteen comments were copies of a second form letter. These and the other twenty commenters raised identical or similar issues. We will therefore address each issue raised.

The Fee Will Unduly Burden Family Members of Inmates

Four commenters expressed concern that the fee would unduly burden family members of inmates.

These comments failed to specify how family members of inmates would bear the ''burden'' of health service fees. If an inmate is classified as indigent and has no funds with which to pay the fee, no fee will be imposed, even though the inmate will still receive necessary health services. There is no apparent cost, therefore, to the inmate's family, who are not required to replenish the inmate's account for the purpose of paying health service fees.

The $2 Fee Is Too High

Twenty-six commenters felt that the $2 fee amount is too high for inmates. One commenter suggested that, since the statute requires that the fee be ''not less than $1.00,'' the fee should be only $1 instead of $2.

The Committee Report accompanying the Act states that ''[t]he amount of the fee is to be determined by the Director of the Bureau of Prisons through regulation.'' *H.R. Rep. No.* 106–851, at 12 (2000). Determination of the fee amount is in the Director's discretion. The Director has determined that a $2 fee is reasonable and is the smallest fee practicable when accounting for the technicalities of processing fees collected for health services.

The Bureau had initially considered a $10 fee. However, when determining the fee amount, the Bureau surveyed amounts charged by states adopting similar policies. Most states that charge a fee for health services impose between $3 and $10 for an inmate-initiated visit, such as Arizona (*Ariz. Rev. Stat.* § 31–161 (2003)), New Hampshire (*N.H. Rev. stat. Ann.* § 622:31–a (2003)), California (*Cal. Penal Code* § 5002.5 (2003)), Delaware (*Del. Code Ann.* tit.1, § 6536 (2003)), Maryland (*Md. Code Ann.*, Corr. Serv. § 2–118 (2003)), Ohio (*Ohio Rev. Code Ann.* § 5120.56 (2002)), and North Dakota (*N.D. Cent. Code* § 12–44.1–12.1 (2003)). In fact, the Bureau's fee is less than the majority of state fees charged for similar purposes.

One commenter recommended that we allow one inmate-initiated health care visit per month with no fee to defray the impact of the fee. This suggestion misunderstands the intent of the rule. Outside of institutions, individuals are not permitted one free health care visit per month. We intend this rule to more accurately reflect life outside the institution, thereby encouraging inmate fiscal responsibility.

Administrative Costs Outweigh Fee Income

Nine commenters argued that the cost to the Bureau of recordkeeping and transferring funds related to the health service fee outweighs the savings resulting from decreased sick-call visits through fee imposition.

The purpose of the rules is to decrease inmate misuse of health services and to encourage fiscal responsibility, not to increase Bureau funding. Any money gained through fees will not be retained by the Bureau. 18 U.S.C. 4048(g)(2) indicates that 75% of amounts collected must ''be deposited in the Crime Victims Fund established under section 1402 of the Victims of Crime Act of 1984 (42 U.S.C. 10601)'' and the remaining 25% must ''be available to the Attorney General for administrative expenses incurred in carrying out this section.'' The 25% reserved for administrative expenses under this subsection goes towards administrative costs associated with dispensing fee amounts to the Crime Victims Fund, and is not kept by the Bureau.

Also, among States and localities that have imposed these fees, reductions in sick call visits from 16 to 50 percent have been realized. In a report included with the legislative history of the Act, the GAO concluded that use of a health care co-payment fee system would reduce the number of unnecessary medical visits in the Federal prison system, perhaps reducing overall visits by as much as 25 percent. *H.R. Rep. No.* 106–851, at 6 (2000), referencing *Federal Prisons: Containing Health Care Costs for an Increasing Inmate Population*, No. GAO/T GGD 00 112, at 3 (April 6, 2000).

Further, according to the legislative history of the Act, the Congressional Budget Office (CBO) expects that imposing such fees would reduce the demand for health care services from Federal prisoners. CBO determined that the reduction in demand would result in possible net savings of up to $5 million annually over the 2001–2005 period, assuming that future appropriations are reduced to reflect the lower health care costs. *H.R. Rep. No.* 106–851, at 9 (2000).

Administrative Process Ineffective to Contest Fee

One commenter felt that the administrative remedy process is ineffective (because of length of time required and the nature of medical problems) to contest a $2 health service fee.

If the nature of an inmate's medical problem requires immediate care, such as for an emergency, or if an inmate is found to be indigent, that inmate will still receive the health care he or she needs. We will not refuse to provide care for an inmate in any situation, even if the inmate contests the applicability of the fee. If an inmate decides to contest the fee through the administrative remedy process, we will not withhold health care services while the administrative remedy claim is pending resolution.

Notice of These Rules Not Given

An inmate commenter stated that there was no written or oral notice of this rule given, ''as required by statute''.

Notice to inmates of this proposed rulemaking under 18 U.S.C. 4048(j) was given to inmates, as required by the statute, as evidenced by this commenter's ability to comment. Also, we accepted comments to the proposed rulemaking approximately 2 months after the official close of the comment period on December 9, 2002. Further, we will issue the notice required by 18 U.S.C. 4048(i) 30 days before implementing the rules and policy requiring a health service fee.

Rules May Cause Further Health Problems

Twenty-eight commenters stated that if an inmate with a contagious disease fails to seek medical attention, simply to save the $2 health service fee, the Bureau may incur more healthcare costs when other inmates and staff become infected.

An inmate who is sick but chooses not to seek medical attention because he or she does not wish to pay the fee does not pose a significant health risk to other inmates or staff, nor does it pose a significant financial risk to the Bureau. The Bureau already has screening mechanisms in place that would prevent the spread of serious contagious diseases. For example, the Bureau has initial intake screening for acute, chronic, mental health and infectious diseases. Also, we require mandatory annual screening for tuberculosis and annual medical examinations for inmates employed in the food service area. Inmates with chronic illnesses such as diabetes, hypertension, thyroid disease, psychiatric illness, etc., are examined at least four times a year as a non-inmate-initiated visit which would not necessitate imposition of a health service fee.

In the Bureau's health care delivery system, each inmate is assigned to a specific health care provider who is responsible for the inmate's on-going health care needs. Each inmate is periodically evaluated by the provider, who is responsible for knowing the circumstances and situation of each of his/her patients. These periodic evaluations are staff-initiated visits which do not trigger the $2 copay fee. Also, as an example of infectious disease detection, an inmate who has been exposed to TB but does not actually have active TB will be evaluated every 90 days.

It would be difficult for an inmate to have an infectious disease for a long time without detection by either the provider assigned to that inmate or staff who interact on a daily basis with that inmate. All staff receive mandatory annual training on the signs and symptoms of infectious diseases. Any staff member can refer an inmate to health services if there appears to be a problem with the inmate's health. If a staff member notices that an inmate looks unhealthy and refers that inmate to the doctor, that visit does not trigger the $2 copay fee under the new regulations.

Rules Violate Due Process Rights

One commenter stated that to deny inmates health care without a hearing is violating their right to due process. The commenter alleges that the rules violate the Due Process Clause of the Fourteenth Amendment of the Constitution.

We believe that this commenter means to allege a violation of the Fifth Amendment to the Constitution, which constrains the power of the Federal Government to deprive any person ''of life, liberty, or property, without due process of law,'' just as the Fourteenth Amendment imposes comparable constraints on the power of the States. *See U.S. v. Balsys*, 118 S.Ct. 2218, at 2236 (1998); *Bolling* v. *Sharpe*, 74 S.Ct. 693 (1958). We therefore respond as though the comment alleged a violation of the Fifth Amendment.

Although inmates have a property interest in the funds in their inmate account, the ''process due,'' for health service fees has been found by many courts to be minimal. Courts have found that as long as inmates are notified that there will be deductions from their accounts for these types of health service fees and that there is an avenue to appeal the fees, no further process is required. *Johnson* v. *Department of Public Safety*, 885 F.Supp. 817 at 821 (D.MD. 1995); *Scott* v. *Angelone*, 771 F.Supp. 1064, 1067–68 (D. Nev.1991) (inmate was not denied due process of law when his account was charged for medical visits because he had prior notice of the policy, authorized the charges and was reimbursed for erroneous charges), *aff'd*, 980 F.2d 738 (9th Cir. 1992); *Gardner* v. *Wilson*, 959 F.Supp. 1224 at 1229 (C.D. CA. 1997); *Bailey* v. *Carter*, No. 99–4282, 2001 WL 845446 (6th Cir. 2001).

Also, inmates are not ''deprived'' of health care. If they cannot pay the fee because they are indigent, or if they require emergency treatment or otherwise fall within the exceptions listed in § 549.72, we will still provide them with necessary health services.

Rules Violate the Eighth Amendment

Fifteen commenters felt that it is unconstitutional to be charged for health services while under the Bureau's care. One stated that 18 U.S.C. 4032 guarantees Federal inmates free medical treatment, and that this rule violates the Eighth Amendment of the Constitution.

The Eighth Amendment of the Constitution prohibits cruel and unusual punishment. With respect to prison medical care, this provision requires that the government and its actors refrain from ''deliberate indifference to an inmate's serious medical needs.'' *Estelle* v. *Gamble*, 429 U.S. 97, 106, 97 S.Ct. 285, 292, 50 L.Ed.2d 251 (1976). Courts typically define ''deliberate indifference'' as treatment ''so grossly incompetent, inadequate, or excessive as to shock the conscience or to be intolerable to fundamental fairness.'' *Miltier* v. *Beorn*, 896 F.2d 848, 851 (4th Cir. 1990). *See also Rogers* v. *Evans*, 792 F.2d 1052, 1058 (11th Cir. 1986).

The Bureau's co-pay rules do not represent treatment that ''shocks the conscience.'' The rules contain several exceptions to avoid imposing unnecessary hardship on indigent, or seriously ill inmates. Our intent is that the rules will only repeatedly affect those inmates who abuse prison medical services with frequent visits for minor complaints. Also, because no inmate will be refused treatment for an inability to pay, our rules will not result in a denial of care, even for inmates who abuse the system.

Several courts have concluded that co-pay requirements for prison medical services are constitutional. Similar policies have been challenged and upheld under the Eighth Amendment. *See Johnson* v. *Department of Public Safety*, 885 F.Supp. 817 at 820–821 (D.MD. 1995); *Gardner* v. *Wilson*, 959 F.Supp. 1224 at 1227–1228 (C.D. Cal. 1997); *Martin* v. *DeBruyn*, 880 F.Supp. 610 at 612 (N.D. Ind. 1995); *Bailey* v. *Carter*, No. 99–4282, 2001 WL 845446 (6th Cir. 2001); *Shapley* v. *Nevada Bd.*

of State Prison Comm'rs, 766 F.2d 404, 408 (9th Cir. 1985).

Rules Violate Article I of the Constitution

One commenter stated that the rule should not apply retroactively (to inmates already sentenced) but only to new inmates, because it amounts to additional punishment. This commenter appears to allege that the rules violate Article I of the Constitution, which provides that neither Congress nor any state shall pass an ex post facto law. Art. I, section 9, cl. 3; Art. I, section 10, cl. 1.

Courts have stated that ''the constitutional prohibition on ex post facto laws applies only to penal statutes which disadvantage the offender affected by them.'' *Collins* v. *Youngblood*, 497 U.S. 37, 41, 110 S.Ct. 2715, 2718, 111 L.Ed.2d 30 (1990). Generally, an ex post facto law ''punishes as a crime an act previously committed, which was innocent when done, which makes more burdensome the punishment for a crime, after its commission, or which deprives one charged with crime of any defense available according to law at the time when the act was committed * * *.'' *Collins*, 497 U.S. at 42, 110 S.Ct. at 2719 (quoting *Beazell* v. *Ohio*, 269 U.S. 167, 169–70, 46 S.Ct. 68, 68–69, 70 L.Ed. 216 (1925)); *see also Gardner* v. *Wilson*, 959 F.Supp. 1224 at 1230 (C.D. Cal. 1997).

Our rule is not an ex post facto law. It is not a criminal statute which disadvantages a criminal offender. These rules do not redefine inmates' crimes or increase inmates' punishment for criminal acts. Also, we do not intend to apply this rule retroactively to events occurring before the date of effectiveness; instead, we will apply the rule only to qualifying health care visits that occur well after inmates have been given notice of this rule, as required by the Act (18 U.S.C. 4048(i)).

Current Medical Care Is Unsatisfactory

Twenty-two commenters complained that the current level of medical care is unsatisfactory.

The healthcare mission of the Bureau of Prisons is to provide appropriate and necessary medical, dental and mental health services to inmates by professional staff. All BOP institutions operate outpatient ambulatory care clinics which are accredited by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), the nation's predominant standards-setting and accrediting body in health care.

Each BOP facility has a Health Services Department, typically staffed with a physician(s) and several mid-level providers, such as physician assistants and nurse practitioners, along with technical and administrative staff. Most Health Services Departments conduct ''sick-call'' four or more days per week for the entire inmate population, and all have 24 hour emergency coverage. All inmates entering our facilities are thoroughly screened by medical staff for physical and mental health conditions, and are monitored thereafter through follow-up appointments and chronic care clinics, as necessary. Inmates who cannot be medically managed as outpatients in our correctional facilities may be designated to one of the BOP's Federal Medical Centers, located throughout the country.

Staff Will Abuse Rules

Two commenters argued that there is potential for staff to abuse the rules by refusing to refer an inmate for a health service visit or by charging them even when they are exempt from the fee under the rule.

Bureau staff are held to the highest standard of professionalism. Although it is arguable that there is always potential for abuse of any rule or staff requirement, the Bureau conducts program reviews and quality control inspections frequently to ensure staff compliance with rules and policy. If an inmate is aggrieved by what he or she perceives as staff abuse of the rules, that inmate should take advantage of our administrative remedy procedures (28 CFR part 542).

DC Interstate Corrections Compact

Thirteen commenters felt that imposing fees on D.C. Code felony offenders violates the Interstate Corrections Compact, D.C. Code § 24.1001, Article I, Article III(A)(1)–(6).

The Interstate Corrections Compact, Article III(a)(1)–(6) does not apply to the Bureau. The Compact addresses arrangements made between the District of Columbia or the Federal Government and any State, and does not impose direct obligations on the Federal Government. Instead, it describes that such arrangements must provide for several points of inmate care, such as ''payments to be made to the receiving State or to the Federal government, by the sending State for inmate maintenance, extraordinary medical and dental expenses, and any participation in or receipt by inmates of rehabilitative or correctional services, facilities, programs, or treatment not reasonably included as part of normal maintenance.''

The Compact, therefore, does not require that the Federal Government pay the cost of inmate maintenance, nor does it preclude inmate health service fees. The Compact only requires that any contract between the State and the Federal Government for the care of State inmates must address the subject of payment for health care. Therefore, this rule does not violate the Compact.

Issues Not Covered in Rules

Four commenters stated that there is no definition of ''indigent'' for the purposes of this rule. Bureau policy will define ''indigent'' inmates as those who had a trust fund account balance of less than $6 for the thirty days before the date of the health service provided.

One commenter complained that the rules do not specifically address dental care. The Bureau's policy that will accompany these rules and be accessible in inmate law libraries will state that health services include medical, mental health and dental care services.

Another commenter stated that there is no definition of ''emergency'' situations in which no fee is imposed. Bureau policy defines ''emergency'' situations as the delivery of care that is ''medically mandatory,'' deemed necessary to maintain or treat a life-threatening illness or injury. Health Services employees are aware of that longstanding definition and will use it to determine whether to charge a fee.

The same commenter stated that there is no definition of ''chronic infectious disease'' for which no health service fee is paid. Again, Bureau policy will state that examples of health care services based on staff referrals, follow-up treatment for chronic conditions, and preventive health care include: Blood pressure checks, glucose monitoring, insulin injections, TB testing, vaccinations, and patient education, etc. We do not place this definition in the rule text because any illness defined as ''chronic infectious disease'' may at any time be no longer considered chronic or infectious, due to frequent breakthroughs in medical research.

For the aforementioned reasons, we adopt the proposed rule, published on October 10, 2002, at 67 FR 63059, as final without change. Please note that this rule is effective and we will begin to implement it on October 3, 2005. We will not implement the provisions of this rule until 30 days after we have given notice of these rules to inmates in our custody, as required by 18 U.S.C. 4048(i)

Executive Order 12866

This regulation has been drafted and reviewed in accordance with Executive Order 12866, ''Regulatory Planning and Review'', section 1(b), Principles of Regulation. The Director, Bureau of

Prisons has determined that this rule is not a ''significant regulatory action'' under Executive Order 12866, section 3(f), and accordingly this rule has not been reviewed by the Office of Management and Budget.

BOP has assessed the costs and benefits of this rule as required by Executive Order 12866 Section 1(b)(6) and has made a reasoned determination that the benefits of this rule justify its costs. The benefits of encouraging inmates to be more responsible for their own health care and reducing inmate abuse of the Bureau's health care system outweigh any perceived costs of imposing the health service fees.

Executive Order 13132

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Under Executive Order 13132, this rule does not have sufficient federalism implications for which we would prepare a Federalism Assessment.

Regulatory Flexibility Act

The Director of the Bureau of Prisons, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), reviewed this regulation. By approving it, the Director certifies that it will not have a significant economic impact upon a substantial number of small entities because: This rule is about the correctional management of offenders committed to the custody of the Attorney General or the Director of the Bureau of Prisons, and its economic impact is limited to the Bureau's appropriated funds.

Unfunded Mandates Reform Act of 1995

This rule will not cause State, local and tribal governments, or the private sector, to spend $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. We do not need to take action under the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 28 CFR Part 549

Prisoners.

Harley G. Lappin,

Director, Bureau of Prisons.

■ Under rulemaking authority vested in the Attorney General in 5 U.S.C. 552(a) and delegated to the Director, Bureau of Prisons, we amend 28 CFR part 549 as follows.

SUBCHAPTER C—INSTITUTIONAL MANAGEMENT

PART 549—MEDICAL SERVICES

■ 1. Revise the authority citation for 28 CFR 549 to read as follows:

Authority: 5 U.S.C. 301; 18 U.S.C. 3621, 3622, 3624, 4001, 4005, 4014, 4042, 4045, 4081, 4082, (Repealed in part as to offenses committed on or after November 1, 1987), 4241–4247, 5006–5024 (Repealed October 12, 1984, as to offenses committed after that date), 5039; 28 U.S.C. 509, 510.

■ 2. Add a new Subpart F to read as follows:

Subpart F—Fees for Health Care Services

Sec.
549.70 Purpose and scope.
549.71 Inmates affected.
549.72 Services provided without fees.
549.73 Appealing the fee.
549.74 Inmates without funds.

§ 549.70 Purpose and scope.

(a) The Bureau of Prisons (Bureau) may, under certain circumstances, charge you, an inmate under our care and custody, a fee for providing you with health care services.

(b) Generally, if you are an inmate as described in § 549.71, you must pay a fee for health care services of $2.00 per health care visit if you:

(1) Receive health care services in connection with a health care visit that you requested, (except for services described in § 549.72); or

(2) Are found responsible through the Disciplinary Hearing Process to have injured an inmate who, as a result of the injury, requires a health care visit.

§ 549.71 Inmates affected.

This subpart applies to:

(a) Any individual incarcerated in an institution under the Bureau's jurisdiction; or

(b) Any other individual, as designated by the Director, who has been charged with or convicted of an offense against the United States.

§ 549.72 Services provided without fees.

We will not charge a fee for:

(a) Health care services based on staff referrals;

(b) Staff-approved follow-up treatment for a chronic condition;

(c) Preventive health care services;

(d) Emergency services;

(e) Prenatal care;

(f) Diagnosis or treatment of chronic infectious diseases;

(g) Mental health care; or

(h) Substance abuse treatment.

§ 549.73 Appealing the fee.

You may seek review of issues related to health service fees through the Bureau's Administrative Remedy Program (see 28 CFR part 542).

§ 549.74 Inmates without funds.

You will not be charged a health care service fee if you are considered indigent and unable to pay the health care service fee. The Warden may establish procedures to prevent abuse of this provision.

[FR Doc. 05–14636 Filed 7–25–05; 8:45 am]

BILLING CODE 4410–05–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[CGD05–05–078]

RIN 1625–AA08

Special Local Regulations for Marine Events; Mill Creek, Fort Monroe, Hampton, VA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary special local regulations during the ''Hampton Cup Regatta'' boat races, a marine event to be held August 12, 13 and 14, 2005, on the waters of Mill Creek, near Fort Monroe, Hampton, Virginia. These special local regulations are necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in portions of Mill Creek during the event.

DATES: This rule is effective from 7:30 a.m. on August 12, 2005 through 6:30 p.m. on August 14, 2005.

ADDRESSES: Documents indicated in this preamble as being available in the docket, are part of docket CGD05–05–078 and are available for inspection or copying at Commander (oax), Fifth