

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854; 24 FR 9565, 3 CFR 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9K, dated August 30, 2002, and effective September 16, 2002, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

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AWP HI E5 Waimea-Kohala, HI [Revised]

Waimea-Kohala Airport, HI

(Lat. 20°00'05" N, long. 155°40'05" W)

Kamuela VOR/DME

(Lat. 19°59'53" N, long. 155°40'12" W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of the Waimea-Kohala Airport and within 2 miles each side of the Kamuela VOR/DME 068° radial, extending from the 6.4-mile radius 12.6 miles northeast of the Kamuela VOR/DME and within 2 miles each side of the Kamuela VOR/DME 246° extending from the 6.4-mile radius to the 13.4 miles southwest of the Kamuela VOR/DME

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Issued in Los Angeles, California, on July 23, 2003.

Stephen J. Lloyd,

*Acting Manager, Air Traffic Division,
Western-Pacific Region.*

[FR Doc. 03–20406 Filed 8–11–03; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 549

[BOP–1086–F]

RIN 1120–AA81

Over-The-Counter (OTC) Medications

AGENCY: Bureau of Prisons, Justice.

ACTION: Final rule.

SUMMARY: In this document, the Bureau of Prisons (Bureau) establishes procedures governing inmate access to Over-The-Counter (OTC) medications. Currently, the inmate population can

only buy approved OTC medications through the commissary at their institutions. Our commissaries will continue to sell medications such as aspirin, acetaminophen, ibuprofen, chlorpheniramine, antacids, hemorrhoidal ointment, hydrocortisone cream, and a fiber supplement (*e.g.* Metamucil®), and other such medications used for symptomatic relief of common conditions. For inmates in inpatient status at our medical referral facilities, we will continue dispensing OTC medications at sick call. For all other inmates, we will continue dispensing OTC medications at sick call to inmates in the general population only if the inmate does not already have the OTC medication, and health services staff determine there is an immediate medical need which must be addressed before the inmate's regularly scheduled commissary visit, or that the inmate has no funds.

We intend that these procedures will help us allocate medical resources efficiently and cost-effectively, while remaining consistent with the Bureau's scope of services which meet inmates' medically mandatory and medically necessary needs.

EFFECTIVE DATE: September 11, 2003.

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: We amend our regulations on Over-The-Counter (OTC) medications (28 CFR part 549, subpart B). We published a proposed rule on this subject in the **Federal Register** on March 1, 1999 (64 FR 10094).

Summary of Public Comment

We received six comments. One generally supported the proposed rule, but five commenters objected.

Citing statutory authority requiring the Bureau to provide for the subsistence of persons charged to its custody, one commenter alleged that the proposed rule promoted the Bureau's economic interests over inmates' health needs and would further erode the quality of health care available to inmates.

This commenter argued that conditions in Bureau facilities leave inmates vulnerable to infection. The commenter further stated that Bureau health services staff do not act responsibly. For example, the commenter states that, at one

institution, sick call appointments may be scheduled 3 to 5 work days after the initial request. The commenter suggests that this is intended to discourage inmates from coming to sick call and that requiring inmates to buy OTC medications would deter inmates from making sick call appointments. The commenter further charges that the Bureau would use profits from the sale of OTC medications to fund tort claim or law suit settlements.

Two additional commenters alleged that costs associated with the upkeep of inmates are the government's responsibility and should remain so. These commenters also objected to the pricing of OTC medications currently available in the institution's commissary. One commenter suggested that if the cost of OTC medications was passed on to the inmate, the inmate should be given a wider choice of medications. The other commenter alleged that staff were likely to abuse the administration of the proposed regulations and that staff improperly followed outdated procedures for addressing inmate complaints. The commenter also criticized the general quality of staff and the level of professional training available to staff.

Another commenter stated that having OTC medications available through the commissary does not justify discontinuing sick call distribution. This commenter states that access to the commissary at some institutions is limited to one scheduled visit per week, that the commissary closes quarterly for inventory, and that the medications are not affordable or are overpriced. This commenter suggested that the proposed procedures may encourage inmates to break other Bureau rules, namely the prohibition on sharing personal property with other inmates.

One commenter believes it is dangerous to permit mental health patients to purchase OTC medications which may adversely interact with prescribed medications. Another also objected to potential negative interactions between prescribed and OTC medications.

Another commenter raised administrative procedural objections to the proposed rule and various Bureau policies for providing inmate health care. This commenter stated that the proposed rule did not cite a need for the change nor expected results from application of the new regulation. The commenter argued that OTC medications can be used for illnesses, and consequently the Bureau is contradicting itself when it states that OTC medications are being used for cosmetic and general hygiene issues.

The commenter also disagreed with the Bureau's assertion that inmate health care conformed to community standards. The commenter criticized the actual provisioning of health care to inmates, citing as an example alleged misdiagnosis of a "rash of illness over night among the prisoners" at a Bureau institution.

Agency Response to Public Comment

Administrative Procedure. Procedures for providing for the health needs of inmates in federal facilities are in the Bureau's Health Services Manual. Because these procedures conform to the community standard of medical care (requiring us to meet inmates' medically mandatory and medically necessary needs), the procedures do not require separate rulemaking.

In instances where correctional management needs require adjustments to the procedures, we do go through rulemaking. For example, special provisions dealing with correctional management needs and chronic infectious disease are in 28 CFR part 549, subpart A.

The provisions for OTC medications are another example where we go through rulemaking because of our correctional management needs. We believe these regulations are necessary to allocate medical resources efficiently and cost-effectively.

The regulation should promote efficiency because Bureau health services staff will not need to see an inmate merely to dispense OTC medications. Health services staff can then devote more time to necessary medical care needs of inmates which they can only address through prescribed medications.

Also, limiting free distribution of OTC medications reduces government expenses. While requiring the inmate to purchase OTC medications may increase costs to the inmate, doing so will prepare inmates for post-incarceration life where individuals have the opportunity and responsibility to address their health care needs through sensible and prudent use of OTC medications.

Providing Health Care. By statute, we must provide for the safekeeping, care, and subsistence of the inmates in our custody. Title 18 of the United States Code, section 4042(a)(2) states that, with regard to inmates, we must "provide for their proper government, discipline, treatment, care, rehabilitation, and reformation."

We disagree with the comments that this rule will compromise our obligation to provide "treatment" and "care" to inmates or that inmates' health is being

used as the target of a money-making enterprise. This rule will, in fact, improve the quality of health care available to inmates: While continuing to meet inmates' medical needs by providing OTC medications in the commissary, we will free valuable medical staff time to more effectively meet inmates' medical needs.

In fact, only OTC medications that are approved by the Pharmacy and Therapeutics Committee (the Bureau's national formulary board) are available for sale in institution commissaries. Under this regulation, our commissaries will continue to sell OTCs such as aspirin, acetaminophen, ibuprofen, chlorpheniramine, antacids, hemorrhoidal ointment, hydrocortisone cream, and a fiber supplement (e.g. Metamucil®), and all other such medications that are available at the institution commissary.

It is consistent with community standards to expect inmates to responsibly, sensibly and prudently use OTC medications. While inmates can get various OTC medications through the institution commissary, some may choose to get these same medications for free through sick call.

The impact for the Bureau's medical resources is not limited merely to the cost of the free OTC medications dispensed at sick call, but also includes health services staff time, which could be more efficiently used during greater medical urgency. An inmate who needs to be evaluated by health care staff ought not to be deterred by the revised procedures. Instead of detracting from our quality of health care, this rule will allow us to use our health care resources where and when the inmates need them the most, thereby improving the quality of health care for inmates.

To clarify that we will still dispense OTC medications to those who do not have ready access to commissary purchases, we state in the rule that it applies to all inmates except those in inpatient status at Federal Medical Centers. Those in inpatient status who, necessarily, do not have commissary access, will receive OTC medications as needed. All other inmates, who have commissary access and are physically able to purchase OTC medications at the commissary will be required to do so by this rule.

Examples cited by some of the commenters of alleged excessive delay in scheduling sick call appointments may well be explained by the need for health services staff to spend time with inmates who attend sick call primarily to receive free OTC medications.

Commissary Sales. National policy established by the FDA and the

Department of Health and Human Services specifies what medical items, including OTC medications, our commissaries may sell, and a national Pharmacy and Therapeutics Committee (a Bureau formulary committee composed of a group of accredited pharmacists) annually reviews and modifies the list of permissible OTC medications. The committee reviews medications to ensure that, before we sell or give them to inmates as "OTC medications", they are dispensed "over the counter" in the public community. In this way, we ensure that we conform to the community standard of medical care. The committee must give us permission before we may sell "OTC medications" to inmates in our commissaries.

We operate the commissary under generally accepted accounting principles. We use profits from commissary sales to provide benefits to inmates in general. We do not use profits to fund tort claim or law suit settlements.

Because of limitations imposed by the correctional setting, the institution commissary cannot offer the variety of items possibly available at local retailers. The commissary does not compete with local retailers, and we are not obligated to provide the lowest price on any particular item.

In any case, as noted above, profits from commissary sales are used for the general benefit of inmates. Even so, we conducted surveys comparing the prices of identical or similar items sold in retail convenience stores and supermarkets in the community surrounding the correctional institutions to assist in pricing policies.

One survey of 50 commissary items was conducted at the following locations: LSCI Allenwood, FPC Alderson, USP Leavenworth, FCI Dublin, FMC Fort Worth, and FCI Miami. We compared the prices of commissary items to identical or similar items in a local retail convenience store and a local supermarket at each location. In 70 percent of the comparisons, we found that the items surveyed were less expensive in the commissaries than in the local convenience stores and supermarkets.

While we limit access to the institution commissary, the proposed regulations allow for exceptions where health services staff determine that the inmate has an immediate medical need which must be addressed before the inmate's regularly scheduled commissary visit (see § 549.30(a)). The proposed regulations also allow for exceptions where the inmate does not have access to the commissary because

the inmate is in administrative detention or special housing.

Inmates Without Funds. The proposed regulations also allow for exceptions to be made for inmates without funds. In the final rule, we define an inmate without funds as one who has had an average daily trust fund account balance of less than \$6.00 for the past 30 days. This definition is similar to that used in the Bureau's inmate telephone regulations (see § 540.105(b)) and in implementing instructions for payment of postage procedures (§ 540.21(d) and (e)). We believe this definition has proved to be both warranted and reasonable.

Interactions. Federal law and Bureau policy addresses issues on drug interactions between prescribed and OTC medications. These laws and our policy require verbal and/or written counseling information for all prescription drugs. When we prescribe such drugs, we give inmates information about potential drug-drug and drug-food interactions, including those with OTC medications.

Also, the regulations specify that Bureau medical centers (that is, the U.S. Medical Center for Federal Prisoners, other Federal Medical Centers, and psychiatric referral centers) will continue dispensing OTC medications through sick call, where inmates taking complex medication regimens, or inmates with cognitive impairments, would be at higher risk of inadvertent drug interactions with OTC medications.

Commissary procedures on the amount of items sold through the commissary serve to minimize the potential for misuse of purchased OTC medications.

Miscellaneous Issues. We believe that our discipline policy (see 28 CFR part 541, subpart B) will discourage inmates from violating Bureau regulations.

Concerns expressed over possible abuse of the administration of the proposed regulations, training available to staff, or over the general quality of staff are not relevant to the procedures of this specific proposed rule. Our administrative remedy program (see 28 CFR part 542) permits inmates to seek formal review of issues which relate to their confinement and is the appropriate channel to seek redress.

One commenter alleged that the administrative remedy program itself is outdated and improperly followed by staff. We disagree. Nevertheless, we will be revising the regulations for the administrative remedy program as part of the "plain language" initiative.

Members of the public may submit further comments concerning this rule

by writing to the previously cited address. We will consider but not respond to these comments in the **Federal Register**.

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 of the 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.

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 § 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.

Plain Language Instructions

We want to make Bureau documents easier to read and understand. If you can suggest how to improve the clarity of these regulations, call or write to Sarah Qureshi at the address or telephone number listed above.

List of Subjects in 28 CFR Part 549

Prisoners.

Harley G. Lappin,

Director, Bureau of Prisons.

■ Under the 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 part 549 to read as follows:

Authority: 5 U.S.C. 301; 18 U.S.C. 3621, 3622, 3624, 4001, 4005, 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 B, consisting of §§ 549.30 and 549.31, to read as follows:

Subpart B—Over-The-Counter (OTC) Medications

Sec.

549.30 Purpose and scope.

549.31 Inmates without funds.

Subpart B—Over-The-Counter (OTC) Medications

§ 549.30 Purpose and scope.

This subpart establishes procedures governing inmate access to Over-The-Counter (OTC) medications for all inmates except those in inpatient status at Federal Medical Centers. Inmates may buy OTC medications which are available at the commissary. Inmates may also obtain OTC medications at sick call if the inmate does not already have the OTC medication and:

(a) Health services staff determine that the inmate has an immediate medical need which must be addressed before his or her regularly scheduled commissary visit; or

(b) The inmate is without funds.

§ 549.31 Inmates without funds.

(a) The Warden must establish procedures to provide up to two OTC medications per week for an inmate without funds. An inmate without funds

is an inmate who has had an average daily trust fund account balance of less than \$6.00 for the past 30 days.

(b) An inmate without funds may obtain additional OTC medications at sick call if health services staff determine that he/she has an immediate medical need which must be addressed before the inmate may again apply for OTC medications under this section.

(c) To prevent abuses of this section (e.g., inmate shows a pattern of depleting his or her commissary funds before requesting OTC medications), the Warden may impose restrictions on the provisions of this section.

[FR Doc. 03-20491 Filed 8-11-03; 8:45 am]

BILLING CODE 4410-05-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD07-03-071]

RIN 1625-AA09

Drawbridge Operation Regulations; Atlantic Intracoastal Waterway, Mile 964.8 at Fort Pierce, St. Lucie County, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily changing the regulations governing the operation of the Fort Pierce North Bridge, mile 964.8, Fort Pierce, Florida. Under this temporary final rule, the bridge need open only a single-leaf every 20 minutes. Double-leaf openings will be available on certain dates with a two-hour advance notice to the bridge tender. This temporary rule is required to allow the bridge owner to safely complete repairs to the bridge.

DATES: This rule is effective from 6 a.m. on August 1, 2003 to 8 p.m. on January 9, 2004.

ADDRESSES: Documents indicated in this preamble as being available in the docket, are part of docket CGD07-03-071, and are available for inspection or copying at Commander (obr), Seventh Coast Guard District, 909 SE. 1st Avenue, Room 432, Miami, FL 33131, between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Lieberum, Project Officer, Seventh Coast Guard District, Bridge Branch at (305) 415-6744.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Publishing an NPRM is impracticable and contrary to the public interest, because it would delay immediate and required repairs to the bridge.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The contractor, PCL, needs to immediately perform necessary repairs to the bridge. In order to do the repairs and ensure worker and public safety, this temporary final rule is required. This temporary rule requires scheduled bridge openings, which provide for the reasonable needs of navigation, and will allow the contractor the time needed to safely repair the bridge.

Background and Purpose

The Fort Pierce North Bridge, mile 964.8 at Fort Pierce, St. Lucie County, Florida, has a vertical clearance of 26 feet at mean high water and a horizontal clearance of 45 feet between the down span and the fender system. The existing operating regulations in 33 CFR 117.5 require the bridge to open on signal.

PCL Contractors notified the Coast Guard that work was needed on the bascule leaves of the Bridge beginning May 5, 2003, and continuing until January 9, 2004. The repair involves welding deck plates, painting, and rebalancing each leaf. In order to provide for worker and public safety, they requested a 20-minute single-leaf opening schedule. Additionally, since both leaves of the Bridge will be unable to open simultaneously, two-hours advance notice will be required to effect a double-leaf opening whenever necessary. However, from 6 a.m. on August 1, 2003, to 6 p.m. on August 10, 2003, the contractor will be performing counterweight girder modifications to the Bridge, and the Bridge will not be able to effect a double-leaf opening at any time during this period, but will open only a single-leaf. This temporary final rule will facilitate immediate and necessary repairs to the Bridge and address worker and public safety issues without significantly hindering navigation.

Discussion of Rule

From 6:01 p.m. August 1, 2003, to 8 p.m. January 9, 2004, this temporary rule requires the Bridge to open a single-leaf on a 20-minute schedule and

provide double-leaf openings with two hours notice to the Bridge tender. This action is necessary to facilitate bridge repairs safely without significantly hindering navigation. During this time of year, the majority of vessels that require a double-leaf opening are traversing the open ocean, and not using the Intracoastal Waterway, due to favorable, seasonal weather.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation is unnecessary, because the rule will affect only a limited amount of marine traffic.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we considered whether this temporary rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities, because the regulations will affect only marine traffic that require double-leaf bridge openings. The impact will be limited to providing a two-hour advance notice to the bridge tender for a double-leaf opening. For a short period, vessels that require double-leaf openings will not be able to pass through at all; however, these types of vessels would most likely be traversing the open ocean and not using the Intracoastal Waterway, due to favorable, seasonal weather.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), we want to assist small entities in understanding this temporary final rule so that they can better evaluate its effects on them and participate in the