## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Parts 808 and 820

**[Docket No. 00N–1561]**

## Exemption From Federal Preemption of State and Local Cigarette and Smokeless Tobacco Requirements; Revocation

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is revoking its regulation governing the exemption from Federal preemption of State and local medical device requirements for the sale and distribution of cigarettes and smokeless tobacco to children and adolescents. This action is being taken in response to the Supreme Court Decision of March 21, 2000, in which the court held that Congress has not given FDA the authority to regulate tobacco products as customarily marketed. On March 31, 2000, FDA removed its regulations restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents. Because these regulations are not in effect, the State requirements are not preempted. Therefore, FDA is revoking its regulations exempting the State and local requirements from preemption. This rule is also adding a regulation that was inadvertently removed in a previous document.

**DATES:** This rule is effective November 7, 2000.

**FOR FURTHER INFORMATION CONTACT:** Rosa M. Gilmore, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2970.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of August 28, 1996 (61 FR 44398), FDA issued a final regulation restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents. In the **Federal Register** of November 28, 1997 (62 FR 63271), FDA issued a final rule granting exemption from preemption under section 521 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360k) for certain cigarette and smokeless tobacco requirements in Alabama, Alaska, and Utah. These requirements were preempted under section 521 of the act because they were different from FDA's requirements but they could be exempted because they were more stringent than FDA's requirements.

On March 21, 2000, in *Food and Drug Administration* vs. *Brown & Williamson Tobacco Corp.*, et al., the Supreme Court ruled that Congress has not granted FDA jurisdiction to regulate tobacco products as customarily marketed. In accordance with this ruling, the agency issued a final rule in the **Federal Register** of March 31, 2000 (65 FR 17135), removing its regulations restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents. The agency inadvertently failed to remove the regulations granting exemptions from Federal preemption for these three States. Because the FDA regulations are not in effect, the State requirements are not preempted and may remain in effect. The agency also inadvertently removed § 820.1(e) (21 CFR 820.1(e)) (65 FR 17135). Section 820.1(e) did not relate to tobacco. Therefore, it is being added in this rule.

### List of Subjects

*21 CFR Part 808*

Intergovernmental relations, Medical devices.

*21 CFR Part 820*

Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 808 and 820 are amended as follows:

## PART 808—EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE REQUIREMENTS

1. The authority citation for 21 CFR part 808 continues to read as follows:

**Authority:** 21 U.S.C. 360j, 360k, 371.

**§ 808.51 [Removed]**

2. Remove § 808.51.

**§ 808.52 [Removed]**

3. Remove § 808.52.

**§ 808.94 [Removed]**

4. Remove § 808.94.

## PART 820—QUALITY SYSTEM REGULATION

5. The authority citation for 21 CFR part 820 continues to read as follows:

**Authority:** 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383.

6. Section 820.1 is amended by adding paragraph (e) to read as follows:

**§ 820.1 Scope.**

* * * * *

(e) *Exemptions or variances.* (1) Any person who wishes to petition for an exemption or variance from any device quality system requirement is subject to the requirements of section 520(f)(2) of the act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in § 10.30 of this chapter, the FDA's administrative procedures. Guidance is available from the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ–220), 1350 Piccard Dr., Rockville, MD 20850, U.S.A., telephone 1–800–638–2041 or 1–301–443–6597, FAX 301–443–8818.

(2) FDA may initiate and grant a variance from any device quality system requirement when the agency determines that such variance is in the best interest of the public health. Such variance will remain in effect only so long as there remains a public health need for the device and the device would not likely be made sufficiently available without the variance.

Dated: October 30, 2000.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 00–28522 Filed 11–6–00; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF VETERANS AFFAIRS

## 38 CFR Part 17

**RIN 2900–AK57**

## VA Payment for Non-VA Public or Private Hospital Care and Non-VA Physician Services That Are Associated With Either Outpatient or Inpatient Care

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Final rule.

**SUMMARY:** This document amends our medical regulations concerning VA payment for non-VA public or private hospital care provided to eligible VA beneficiaries. This document also amends our medical regulations concerning VA payment for non-VA physician services that are associated with either outpatient or inpatient care provided to eligible VA beneficiaries at non-VA facilities. With certain exceptions, these payments have been based on Medicare methodology. Sometimes VA can negotiate contracts with hospitals or physicians or with their agents to reduce the payment amounts. This document amends these

regulations to allow VA to make lower payments based on such negotiations.

**DATES:** *Effective Date:* November 7, 2000.

**FOR FURTHER INFORMATION CONTACT:** Tony Guagliardo, Health Administration Service, (10C3), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–8307. (This is not a toll-free number.)

**SUPPLEMENTARY INFORMATION:**

**Administrative Procedure Act**

This document allows VA to pay hospitals and physicians the amount that they on their own or through agents have negotiated to receive from VA. Accordingly, this document reflects contract actions that are exempt from the prior notice-and-comment and delayed effective date provisions of 5 U.S.C. 553.

**Unfunded Mandates**

The Unfunded Mandates Reform Act requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector of $100 million or more in any given year. This rule would have no consequential effect on State, local, or tribal governments.

**Regulatory Flexibility Act**

The Secretary hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This rule would affect only a small portion of the business of the affected entities. Accordingly, pursuant to 5 U.S.C. 605(b), this rule is exempt from the initial and final regulatory flexibility analysis requirements of §§ 603 and 604.

**Catalog of Federal Domestic Assistance Numbers**

The Catalog of Federal domestic assistance numbers for the programs affected by this rule are 64.005, 64.007, 64.008, 64.009, 64.010, 64.011, 64.012, 64.013, 64.014, 64.015, 64.016, 64.018, 64.019, 64.022, and 64.025.

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

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

Approved: October 31, 2000.

**Hershel W. Gober,**

*Acting Secretary of Veterans Affairs.*

For the reasons set out in the preamble, 38 CFR part 17 is amended as set forth below:

## PART 17—MEDICAL

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

**Authority:** 38 U.S.C. 501, 1721, unless otherwise noted.

2. In § 17.55, a new paragraph (k) is added; and the authority citation at the end of the section is revised, to read as follows:

**§ 17.55 Payment for authorized public or private hospital care.**

* * * * *

(k) Notwithstanding other provisions of this section, VA, for public or private hospital care covered by this section, will pay the lesser of the amount determined under paragraphs (a) through (j) of this section or the amount negotiated with the hospital or its agent.

(Authority: 38 USC 513, 1703, 1728; § 233 of P. L. 99–576)

3. Remove the undesignated center heading immediately before § 17.56.

4. In § 17.56, a new paragraph (e) is added to read as follows:

**§ 17.56 Payment for non-VA physician services associated with outpatient and inpatient care provided at non-VA facilities.**

* * * * *

(e) Notwithstanding 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 (d) of this section or the amount negotiated with the physician or the physician's agent.

(Authority: 38 U.S.C. 513, 38 U.S.C. 1703, 38 U.S.C. 1728)

5. Add an undesignated center heading immediately before § 17.57 to read as follows:

**Use of Community Nursing Home Care Facilities.**

[FR Doc. 00–28472 Filed 11–06–00; 8:45 am]

BILLING CODE 8320–01–P

## LEGAL SERVICES CORPORATION

### 45 CFR Part 1628

### Recipient Fund Balances

**AGENCY:** Legal Services Corporation.

**ACTION:** Final rule.

**SUMMARY:** This final rule revises the Corporation's rule on recipient fund balances to provide the Corporation with more discretion to determine whether to permit a recipient to maintain a fund balance of up to 25% of its LSC support for a particular reporting period and to specify a limited number of extraordinary and compelling circumstances for which LSC has discretion to permit a recipient to maintain a fund balance in excess of 25% of its LSC support. The final rule also adds additional requirements and limitations applicable to waiver requests and the use of excess fund balances. Finally, the rule is restructured for clarity and for consistency with other Corporation regulations.

**EFFECTIVE DATE:** This final rule is effective on December 7, 2000.

**FOR FURTHER INFORMATION CONTACT:** Victor M. Fortuno, Vice President for Legal Affairs, Legal Services Corporation, 750 First Street, NE.—Suite 1000, Washington, DC 20002–4250; 202–336–8800.

**SUPPLEMENTARY INFORMATION:** On September 11, 1998, the Operations and Regulations Committee (''Committee'') of the Legal Services Corporation (''LSC'' or ''the Corporation'') Board of Directors (''Board'') met to consider proposed revisions to the Corporation's rule governing recipient fund balances, 45 CFR part 1628. The Committee adopted a proposed rule that was published in the **Federal Register** for public comment at 63 FR 56591 (October 22, 1998). Nineteen comments were received and considered by the Corporation.

Following the close of the comment period, the Committee met on February 21, 1999, to review the public comment on the proposed rule. No action was taken on the proposed rule at that time as the Committee was advised by the Corporation's staff that additional time was needed to consider fully a number of issues raised by the public comment and to formulate informed recommendations for the Committee's consideration in adopting a final rule.

The Committee was briefed by staff on two issues raised by one commenter which challenged the legal sufficiency of the proposed rulemaking and the legal authority for the Corporation to permit any carryover of fund balances