DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 808 and 820

[Docket No. 00N–1551]

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. Therefore, under the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j, 360k, 371), 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 Parts 808

Intergovernmental relations, Medical devices.

21 CFR Part 820

Medical devices, Reporting and recordkeeping requirements.

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:


§ 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.


Margaret M. Dotzel, Associate Commissioner for Policy.

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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