

## REPORT ON HUMANITARIAN DEVICE EXEMPTIONS

Pub. L. 101-629, §14(c), Nov. 28, 1990, 104 Stat. 4525, directed Secretary of Health and Human Services, within 4 years after issuance of regulations under 21 U.S.C. 360j(m)(6), to report to Congress on types of devices exempted, an evaluation of effects of such section, and a recommendation on extension of the section.

## REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

**§ 360k. State and local requirements respecting devices****(a) General rule**

Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
- (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

**(b) Exempt requirements**

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

- (1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or
- (2) the requirement—
  - (A) is required by compelling local conditions, and
  - (B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

(June 25, 1938, ch. 675, §521, as added Pub. L. 94-295, §2, May 28, 1976, 90 Stat. 574.)

**§ 360I. Postmarket surveillance****(a) Postmarket surveillance****(1) In general****(A) Conduct**

The Secretary may by order, at the time of approval or clearance of a device or at any time thereafter, require a manufacturer to conduct postmarket surveillance for any device of the manufacturer that is a class II or class III device—

- (i) the failure of which would be reasonably likely to have serious adverse health consequences;
- (ii) that is expected to have significant use in pediatric populations; or

(iii) that is intended to be—

- (I) implanted in the human body for more than 1 year; or
- (II) a life-sustaining or life-supporting device used outside a device user facility.

**(B) Condition**

The Secretary may order a postmarket surveillance under subparagraph (A) as a condition to approval or clearance of a device described in subparagraph (A)(ii).

**(2) Rule of construction**

The provisions of paragraph (1) shall have no effect on authorities otherwise provided under the<sup>1</sup> chapter or regulations issued under this chapter.

**(b) Surveillance approval****(1) In general**

Each manufacturer required to conduct a surveillance of a device shall, within 30 days of receiving an order from the Secretary prescribing that the manufacturer is required under this section to conduct such surveillance, submit, for the approval of the Secretary, a plan for the required surveillance. The Secretary, within 60 days of the receipt of such plan, shall determine if the person designated to conduct the surveillance has appropriate qualifications and experience to undertake such surveillance and if the plan will result in the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health. The manufacturer shall commence surveillance under this section not later than 15 months after the day on which the Secretary issues an order under this section. Except as provided in paragraph (2), the Secretary, in consultation with the manufacturer, may by order require a prospective surveillance period of up to 36 months. Except as provided in paragraph (2), any determination by the Secretary that a longer period is necessary shall be made by mutual agreement between the Secretary and the manufacturer or, if no agreement can be reached, after the completion of a dispute resolution process as described in section 360bbb-1 of this title.

**(2) Longer surveillance for pediatric devices**

The Secretary may by order require a prospective surveillance period of more than 36 months with respect to a device that is expected to have significant use in pediatric populations if such period of more than 36 months is necessary in order to assess the impact of the device on growth and development, or the effects of growth, development, activity level, or other factors on the safety or efficacy of the device.

**(c) Dispute resolution**

A manufacturer may request review under section 360bbb-1 of this title of any order or condition requiring postmarket surveillance under this section. During the pendency of such review, the device subject to such a postmarket

<sup>1</sup> So in original. Probably should be “this”.