

companion proposed rule and the direct final rule will be considered comments on the proposed rule.

#### List of Subjects in 21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of the Food and Drugs, 21 CFR part 814 is amended as follows:

#### PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

1. The authority citation for 21 CFR part 814 continues to read as follows:

**Authority:** 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381.

2. Section 814.39 is amended by revising the introductory text of paragraph (a) and paragraph (a)(4) and by adding paragraph (f) to read as follows:

##### § 814.39 PMA supplements.

(a) After FDA's approval of a PMA, an applicant shall submit a PMA supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA, unless the change is of a type for which FDA, under paragraph (e) of this section, has advised that an alternate submission is permitted or is of a type which, under section 515(d)(6)(A) of the act and paragraph (f) of this section, does not require a PMA supplement under this paragraph. While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device:

\* \* \* \* \*

(4) Changes in manufacturing facilities, methods, or quality control procedures that do not meet the requirements for a submission under paragraph (e) or (f) of this section.

\* \* \* \* \*

(f) Under section 515(d) of the act, modifications to manufacturing procedures or methods of manufacture that affect the safety and effectiveness of a device subject to an approved PMA do not require submission of a PMA supplement under paragraph (a) of this section and are eligible to be the subject of a 30-day notice. A 30-day notice shall describe in detail the change,

summarize the data or information supporting the change, and state that the change has been made in accordance with the requirements of 21 CFR part 820. The manufacturer may distribute the device 30 days after the date on which FDA receives the 30-day notice, unless FDA notifies the applicant within 30 days from receipt of the notice that the notice is not adequate. If the notice is not adequate, FDA shall inform the applicant in writing that a 135-day PMA supplement is needed and shall describe what further information or action is required for acceptance of such change. The number of days under review as a 30-day notice shall be deducted from the 135-day PMA supplement review period if the notice meets appropriate content requirements for a PMA supplement.

Dated: March 24, 1998.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 98–11086 Filed 4–24–98; 8:45 am]

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#### DEPARTMENT OF JUSTICE

##### Office of the Attorney General

##### 28 CFR Part 0

[Order No. 2147–98]

##### Delegation of Power of the Attorney General Respecting Transfer of Offenders To or From Foreign Countries

**AGENCY:** Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** Section 0.64–2 of Title 28, Code of Federal Regulations, delegates to the Assistant Attorney General in charge of the Criminal Division all of the powers conferred on the Attorney General under 18 U.S.C. 4102 that have not been delegated to the Director of the Bureau of Prisons, including the authority to find appropriate or inappropriate the transfer of offenders to or from a foreign country under a treaty as referred to in Pub. L. 95–144. The section also authorizes the Assistant Attorney General in charge of the Criminal Division to redelegate this authority to the Deputy Assistant Attorneys General of the Criminal Division, the Senior Associate Director of the Office of Enforcement Operations in the Criminal Division, and, in the Senior Associate Director's absence, to the Director of the Office of Enforcement Operations. This final rule amends 28 CFR 0.64–2 by authorizing the Assistant Attorney General in charge of the

Criminal Division to additionally redelegate this authority to the Director of the Office of Enforcement Operations and the Associate Directors of the Office of Enforcement Operations, and eliminating the requirement that the Senior Associate Director of the Office of Enforcement Operations be absent for this further redelegate to be effective. This rule is intended to provide greater flexibility within the Office of Enforcement Operations with respect to the management of the prisoner transfer program, reflecting an increase in both the number and complexity of our treaty relationships, and the related workload handled by the Office of Enforcement Operations.

**EFFECTIVE DATE:** April 15, 1998.

##### FOR FURTHER INFORMATION CONTACT:

Frederick D. Hess, Director, Office of Enforcement Operations, Criminal Division, Department of Justice, Washington, DC 20530; 202–514–6809.

**SUPPLEMENTARY INFORMATION:** The Assistant Attorney General currently is authorized under 28 CFR 0.65–02 to redelegate his authority to find appropriate or inappropriate the transfer of offenders to or from a foreign country under certain treaties to his Deputy Assistant Attorneys General, the Senior Associate Director, Office of Enforcement Operations, and, in the absence of the Senior Associate Director, the Director of the Office of Enforcement Operations. This final rule permits redelegate of this authority to the Director and Associate Directors of the Office of Enforcement Operations, regardless of whether the Senior Associate Director is absent.

This rule is a matter of internal Department management.

It has been drafted and reviewed in accordance with section 1(b) of Executive Order 12866. It has been determined that this rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866 and, accordingly, this rule has not been reviewed by the Office of Management and Budget, and no regulatory impact analysis has been prepared.

In accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612; specifically at section 605(b)), the Attorney General has reviewed this rule and, by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

This rule will not have a substantial direct impact upon the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various

levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Act of 1996. This rule will not result in an annual effect on the economy of \$100 million 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 0

Authority delegations (Government agencies), Government employees, Organization and functions (Government agencies), Prisoners, Whistleblowing.

For the reasons stated in the preamble, Title 28, Part 0, Subpart K of the Code of Federal Regulations is amended as follows:

#### PART 0—[AMENDED]

1. The authority citation for Part 0 continues to read as follows:

**Authority:** 5 U.S.C. 301; 28 U.S.C. 509, 510, 515–519.

2. Section 0.64–2 is amended as follows:

a. The phrase “Public Law 95–44” is removed and the phrase “Public Law 95–144” is inserted in its place;

b. The final sentence is revised to read as follows:

#### § 0.64–2 Delegation respecting transfer of offenders to or from foreign countries.

\* \* \* The Assistant Attorney General in charge of the Criminal Division is authorized to redelegate this authority to his Deputy Assistant Attorneys

General, the Director of the Office of Enforcement Operations, and the Senior Associate Director and Associate Directors of the Office of Enforcement Operations.

Dated: April 15, 1998.

**Janet Reno,**

*Attorney General.*

[FR Doc. 98–10832 Filed 4–24–98; 8:45 am]

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#### FEDERAL COMMUNICATIONS COMMISSION

##### 47 CFR Part 69

[CC Docket 96–128; DA 98–481]

#### Implementation of the Pay Telephone Reclassification and Compensation Provisions of the Telecommunications Act of 1996

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule; clarification and waivers.

**SUMMARY:** The Common Carrier Bureau adopted a Memorandum Opinion and Order, which clarifies the requirements for the provision of payphone-specific coding digits by local exchange carriers (LECs) and payphone service providers (PSPs) to interexchange carriers (IXCs). The order also clarifies that automatic number identification indicators (“ANI ii”) and flexible automatic numbering identification (“FLEX ANI”), are the methods to provide payphone-specific coding digits that comply with the requirements of the *Payphone Orders*. In addition, the order clarifies the tariff requirements that LECs must file pursuant to the *Payphone Orders*. The order also grants a waiver of part 69 of the Commission’s rules so that LECs can establish rate elements to recover the costs of implementing FLEX ANI to provide payphone-specific coding digits

for per-call compensation. Additionally, this order provides limited waivers to LECs, PSPs, and IXCs, when appropriate, to facilitate the implementation of per call compensation.

**DATES:** Effective March 9, 1998.

**FOR FURTHER INFORMATION CONTACT:** Rose Crellin, Formal Complaints and Information Branch, Enforcement Division, Common Carrier Bureau (202) 418–0960.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Bureau’s Memorandum Opinion and Order in CC Docket No. 96–128 [DA 98–481], adopted on March 9, 1998, and released on March 9, 1998. The full text of the Memorandum Opinion and Order (“Order”) is available for inspection and copying during normal business hours in the FCC Reference Center, Room 239, 1919 M Street, N.W., Washington, D.C. The complete text of this decision also may be purchased from the Commission’s duplicating contractor, International Transcription Services, 1231 20th Street, N.W., Washington, D.C. 20036.

#### Paperwork Reduction Act

The Federal Communications Commission has received Office of Management and Budget (OMB) approval for the following public information collections contained in the Order pursuant to the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid control number.

**OMB Control Number:** 3060–0823.

**Expiration Date:** 09/30/98.

**Title:** Pay Telephone Reclassification Memorandum Opinion and Order, CC Docket No. 96–128.

**Form No.:** N/A.

**Respondents:** Business or other for-profit entities.

Information collection requirement	No. of respondents (approximately)	Est. time per response (hours)	Total annual burden
a. LEC Tariff To Provide FLEX ANI to IXCs .....	400	35	14,000
b. LEC Tariff To Recover Costs .....	400	35	14,000
c. LECS Must Provide IXCs on Payphones that Provide Payphone specific Coding Digits .....	400	24	9,600
d. LECs must Provide IXCs and PSPs Information on where FLEX ANI is Available Now and When it is to be Scheduled in the Future .....	400	16	6,400
e. Waiver; LECs to Provide Cost Analysis Upon Request .....	20	35	700

**Total Annual Burden:** 44,700 Hours.  
**Estimated Annual Reporting and Recordkeeping cost Burden:** \$0.  
**Needs and Uses:** In the MO&O, the Bureau clarifies and provides waivers of

requirements established in the Payphone Orders for the provision of payphone-specific coding digits by LECs and PSPs, to IXCs, beginning October 7,

1997. The information disclosure rules and policies governing the payphone industry to implement Section 276 of the Act will ensure the payment per-call