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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 100

RIN 0906–AA36

National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table—II

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final rule.

SUMMARY: The Secretary has made findings as to certain illnesses and conditions that can reasonably be determined in some circumstances to be caused or significantly aggravated by certain vaccines. Based on these findings, the Secretary is amending, by final rule, the existing regulations governing the National Vaccine Injury Compensation Program (VICP) by revising the Vaccine Injury Table (Table) as authorized under section 313 of the National Childhood Vaccine Injury Act of 1986 and section 2114 (c) and (e) of the Public Health Service Act (the Act).

The VICP provides a system of no-fault compensation for certain individuals who have been injured by specific childhood vaccines. The Vaccine Injury Table included in the Act establishes presumptions about causation of certain illnesses and conditions, which are used by the Court to adjudicate petitions.

EFFECTIVE DATE: This regulation is effective March 24, 1997.

FOR FURTHER INFORMATION CONTACT: Geoffrey Evans, M.D., Chief Medical Officer, Division of Vaccine Injury Compensation, Bureau of Health Professions, (301) 443–4198, or David Benor, Senior Attorney, Office of the General Counsel (301) 443–2006.

SUPPLEMENTARY INFORMATION:

Introduction and Procedural History

On November 8, 1995, the Assistant Secretary for Health, with the approval of the Secretary of Health and Human Services (the Secretary), published in the Federal Register (60 FR 56289) A Notice of Proposed Rulemaking (NPRM) to amend the Vaccine Injury Table (the Table) and to revise the Qualifications and Aids to Interpretation of the Table (Qualifications and Aids). The NPRM was issued pursuant to section 2114(c) of the Act, which authorizes the Secretary to promulgate regulations to modify the Table, and section 2114(e), which directed the Secretary to add to the Table, by rulemaking, coverage of additional vaccines which are recommended by the Centers for Disease Control and Prevention for routine administration to children.

As stated in the preamble to the NPRM, under section 313 of the Act, Congress mandated that the Secretary review the scientific literature and other relevant information to determine whether, based upon the available evidence, a causal relationship exists between certain adverse events examined and exposure to vaccines against diphtheria, measles, mumps, poliomyelitis, and tetanus. The review was broadened to include the vaccines against hepatitis B, and Hemophilus influenzae type b (Hib). The Secretary entered into a contract with the Institute of Medicine (IOM), as recommended by Congress, to perform this review. The IOM issued its findings in a report entitled *Adverse Events Associated with Childhood Vaccines; Evidence Bearing on Causality*. (Institute of Medicine, K.R. Stratton, C.J. Howe, R.B. Johnson, Eds., 1994.) Upon consideration of the IOM report, consultations with the Advisory Committee on Childhood Vaccines (ACCV), and the National Vaccine Advisory Committee (NVAC), and review of other relevant scientific information, the Secretary published the proposed changes to the Table and the Qualifications and Aids.

There was a 6-month comment period after publication. The Secretary received three written comments in response to the NPRM. A public hearing was scheduled for February 29, 1996, as announced in the Federal Register on February 5, 1996 (61 FR 4249), but no individual or organization appeared to testify.

One of the commenters, an association representing pediatricians, extended its full support for the proposed additions and revisions to the Table.

A second comment was submitted by a manufacturer of several childhood vaccines. The manufacturer's comment was that the proposed revisions to the Table did not definitively state how the proposed revisions would affect persons who have pending civil actions against vaccine manufacturers or administrators when the revisions to the Table become effective. The manufacturer suggested that language should be added to the rule which affirmatively gives plaintiffs in the tort system the ability to file a claim, within 2 years after the effective date of the revision or before judgment, if the injury or death allegedly attributable to the vaccine occurred no more than 8 years before the effective date of the revision. Section 2116(b) of the Act provides a 2-year period after the effective date of a revision to the Table for a petition to be filed based on the revision. The injury or death alleged to be related to the vaccine must have occurred no more than 8 years before the date of the revision. However, section 2111(a)(5)(B) of the Act states that ''[i]f a plaintiff has pending a civil action for damages for a vaccine-related injury or death, such person may not file a petition under the subsection (b) (of the Act) for such injury or death.'' reading these provisions together, it appears that if a plaintiff in such a case dismisses the civil action and files a Program petition within the applicable time limit, the petition may proceed. (If the civil action led to an award of damages or a settlement, section 2111(a)(7) of the Act would prohibit the filing of the petition.) In the light of these statutory provisions, we believe that the issue raised by the commenter is adequately addressed.

The final comment was from a group representing vaccine-injured persons and their families. The group had comments in several areas. The Secretary has carefully considered these comments and responds to them below. The first assertion of the group was that two independent IOM committees concluded that the scientific evidence favors a causal relationship between oral polio vaccine and tetanus vaccine and Guillain-Barre Syndrome (GBS). The commenter questions why, given this information, the Secretary is proposing to remove GBS from the Table. First, it is worth noting that this condition has never been included in the Table. Moreover, the preamble to the NPRM explained in detail the Department's reasons for proposing not to extend the Table's coverage to this condition. (60 FR 56292–3 and 56296–7.) The commenter's reference to the IOM committee's report does not provide a sufficient basis to reverse the Department's analysis, given that this analysis fully considered the IOM committee's report, as well as other relevant data.

The commenter's second concern asked for an explanation of why anaphylaxis is the only Table injury for hepatitis B vaccine when the IOM review stated that no scientific studies have been conducted to determine if there is a causal relationship between hepatitis B and arthritis, Sudden Infant Death Syndrome (SIDS), GBS, myoptic (sic: optic) neuritis, multiple sclerosis, transverse myelitis or other central

demyelinating disease. Similarly, the group questions why there is no Table injury for Hemophilus influenzae type b (Hib) vaccine when no scientific studies have been done to determine whether there is a causal connection between the Hib vaccine and transverse myelitis, GBS, thrombocytopenia, anaphylaxis and SIDS. The Secretary is charged with revising the Table where such revisions are in keeping with scientific evidence. The goal is to have the Table and Qualifications and Aids reflect current scientific knowledge on the relationship between certain adverse events and covered vaccines. Where that scientific research concerning the relationship between a disorder and a vaccine is incomplete or nonexistent, the Secretary believes it would be inappropriate and inconsistent with her statutory responsibility to revise the Table to establish a presumption that a relationship exists.

The group also commented upon the ability of the Vaccine Adverse Events Reporting System (VAERS) to capture adequately the frequency and severity of vaccine reactions. VAERS is a passive reporting system for events that are temporally related to vaccine administration. *See* section 2125 of the Act. VAERS is not, however, a matter within the scope of this rulemaking.

Finally, the group states that no vaccine should be added to the Table until credible scientific studies have been conducted to determine which chronic health problems are being caused by new vaccines. Under section 2114(e) of the Act, the Secretary is required to revise the Table to include vaccines recommended to the Secretary by the Centers for Disease Control and Prevention (CDC), for routine administration to children. If the scientific evidence is insufficient to establish that an illness or condition is associated with such a vaccine, then it is appropriate to include the vaccine on the Table without establishing that such illness or condition is presumed to be caused by the vaccine. The addition of vaccines to the Table allows individuals alleging injury by such vaccines to file petitions for compensation and to prevail on the basis of the Act's ''causation in fact'' standard. *See* section 2111(c)(1)(C)(ii)(I) of the Act. Such petitioners benefit from participating in the Program in that they need not show negligence or some other standard of liability, as would be required in a civil action. Should the Department learn that these new vaccines have associated illnesses or conditions, rulemaking will be initiated to amend the Table.

Other Information

The Act provides that a revision to the Table based on the addition of vaccines under section 2114(e) of the Act shall take effect upon the effective date of a tax enacted to provide funds for compensation for injuries from vaccines that are added to the Table. *See* section 13632(a)(3) of the Omnibus Budget Reconciliation Act of 1993, Pub. L. 103–66 enacted August 10, 1993. The tax for the hepatitis B, the Hib and the varicella vaccines has not been enacted yet; accordingly, claimants alleging an injury or death as a result of a hepatitis B, Hib, or varicella vaccination will not have a cause of action against the Secretary until the tax is enacted and become effective. *See* § 100.3(c)(2). However, the other changes to the Qualifications and Aids to Interpretation of the Table and the addition of certain illnesses, disabilities or conditions to the Table, e.g., brachial neuritis as a Table injury for DPT, will become effective on March 24, 1997. *See* § 100.3(c)(1). Thus, there will be some delay between the time the final rule becomes effective and the time the hepatitis B, Hib, and varicella vaccines provide a cause of action for petitioners. As soon as the tax becomes effective, a petitioner may file a claim for an injury or death allegedly caused by these vaccines. The Clerk of the U.S. Court of Federal Claims will determine how a filing will be processed when a petitioner files a claim for hepatitis B, Hib, or varicella injuries before the tax becomes effective.

Hemophilus Influenzae Type B (Hib) Vaccine

As noted in the preamble to the NPRM (p. 56297), unconjugated Hib polysaccharide vaccine (PRP) was found to be associated with early onset invasive Hib disease. As discussed elsewhere in this preamble, the option to file a petition for an injury associated with vaccines now being added to the Table is limited to cases based on vaccine-related injuries or deaths that occurred within the 8-year period before the effective date of the addition. As almost all cases of early onset invasive Hib disease which are vaccine-related will be associated with vaccines given before December 1987 (when the Hib conjugate vaccine took the place of the PRP vaccine for routine administration), the result of this 8-year limitation means that the likely cases of this vaccine-associated condition will not be able to file for compensation under the Program, absent a change to the statute. Nevertheless, we are retaining this as a Table injury in case the vaccine has been administered within the 8-year period or is administered in the future.

Varicella Vaccine

As provided in the NPRM, the Table includes any new vaccine recommended by the CDC for routine administration to children. Since the publication of the NPRM, CDC has recommended the varicella vaccine for routine administration to children and, consistent with the Secretary's obligations under section 2114(e), the varicella vaccine has been added to the Table as item XI. No adverse reactions for the varicella vaccine are being added to the table, as there is no evidence of any serious illness or condition related to this vaccine. However, should the Department become aware of any adverse events associated with the varicella vaccine, rulemaking will be initiated to revise the Table accordingly.

Technical Amendments

In the Notice of Proposed Rulemaking published in the Federal Register on November 8, 1995, items I.C, II.C., III.C., IV.B, and V.C. of the Table read: ''[a]ny sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.'' These items are being revised to read: ''[a]any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.'' The additional language does not represent a change in the available Table injuries; rather, the language is added to provide internal consistency within the Table. In addition, because the varicella vaccine has been added to the Table as item XI, former item XI designated in the NPRM is now renumbered as item XII in the final rule. Further, we have revised the format of the Table to make it more readable.

Finally, as we indicated in the preamble to the 1995 regulation, we did not intend that hospitalization be viewed as an absolute requirement to establish an acute encephalopathy, but rather as an indicator of the severity of the acute event. (See the qualifications and aids to interpretation at § 100.3 (b)(2)(i)). To allay concerns in this regard, we have made this explicit in the regulation itself by adding the following parenthetical phrase at the end of the sentence in paragraph (i): ''whether or not a hospitalization occurred''.

Guidelines

As noted in the NPRM, section 313 requires that the Secretary establish guidelines based on the results of the 313 report ''respecting the administration'' of the vaccines that were reviewed, which guidelines shall include:

''(i) The circumstances under which any such vaccine should not be administered,

''(ii) The circumstances under which administration of any such vaccine should be delayed beyond its usual time of administration, and

''(iii) The groups, categories, or characteristics of potential recipients of such vaccine who may be at significantly higher risk of major adverse reactions to such vaccine than the general population of potential recipients.''

We have examined the recommendations of the Advisory Committee on Immunization Practices (ACIP) of the CDC, as set forth in the Morbidity and Mortality Weekly Reports Recommendations and Reports, dated September 6, 1996 entitled, ''Update: Vaccine Side Effects, Adverse Reactions, Contraindications and Precautions.'' Members of the public may obtain copies of the report by writing to MS Publications, C.S.P.O. Box 9120, Waltham, MA 02254, telephone 1–800–843–6356, 617–893–3800 (Massachusetts). The cost of the publication is $4.00. It may be obtained without charge through use of the World-Wide Web (WWW). The address is ''http://www.cdc.gov/epo/mmwr/mmwr__rr.html.'' We find that the ACIP recommendations are consistent with the findings that the Department made as part of section 313 NPRM and this final rule, and that they satisfy the statutory requirements for guidelines. Accordingly, we proposed that the ACIP recommendations will constitute the guidelines called for by section 313.

Section 313 calls for consultation with the ACCV and notice and opportunity for public hearing with respect to these guidelines. The ACIP recommendations were submitted to the ACCV at its meeting of June 6–7, 1996. We will also offer the opportunity for public comment on the use of the ACIP recommendations as the section 313 guidelines at a hearing which we anticipate will be scheduled in conjunction with a future ACCV meeting. A separate notice will be published in the Federal Register to invite public comment at that hearing. After consideration of any comments which we receive, we will publish a notice about the final adoption of these guidelines.

Future revisions of the ACIP recommendations will also be effective for 313 purposes and a notice to that effect will accompany the publication of the ACIP recommendations in the MMWR.

Economic Impact

The Secretary certifies that this final rule will not have a significant impact on a substantial number of small businesses, because it will have only small effects, and those primarily on individuals. The effects will be primarily on the ability of certain individuals to obtain compensation without having a burden of proving causation in fact. Attorneys who represent such individuals will be affected only to the extent that they may have a harder or easier burden of proof with respect to the petitions filed. However, under section 2115(e) of the Act, in almost all cases, attorneys' reasonable fees and costs are reimbursed from the Vaccine Injury Compensation Trust Fund.

Executive Order 12866 requires that all regulations reflect consideration of alternatives, of costs, of benefits, of incentives, of equity, and of available information. Regulations must meet certain standards, such as avoiding unnecessary burden. Regulations which are ''significant'' because of cost, adverse effects on the economy, inconsistency with other agency actions, effects on the budget, or novel legal or policy issues, require special analysis.

As stated above, this final rule would modify the Vaccine Injury Table based on legal authority, and under that authority the Court will award such fees and costs as appropriate under the law. As such, the regulation would have little direct effect on the economy or on Federal or State expenditures. For the same reasons, the Secretary has also determined that this is not a ''significant'' rule under Executive Order 12866.

Effect of the New Rule

The final rule will have an effect for individuals who were not eligible to file petitions based on the earlier versions of the Vaccine Injury Table, but who may be eligible to file petitions based on the revised Table. The Act permits such individuals to file a petition for such compensation not later than 2 years after the effective date of the revision if the injury or death occurred not more than 8 years before the effective date of the revision of the Table. *See* 42 U.S.C. 300aa–16(b). As part of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66), Congress amended this section to permit individuals to file claims within this 2-year period, even if they had already filed a claim involving a particular vaccine, but only if the Table revision will ''significantly increase the likelihood of obtaining compensation.'' *See* Pub. L. 103–66, sec. 13632(a)(1). For example, this amendment would permit an individual whose claim alleging MMR vaccine-related thrombocytopenic purpura had been dismissed by the Claims Court to file a new claim for the same vaccine-related injury, if the individual can show that the addition of thrombocytopenic purpura to the Table as a MMR vaccine-related condition has significantly increased the likelihood of obtaining compensation.

Possible Effect on Other Legislation

This rule will not have an effect on the Vaccine for Children Program, implemented by the CDC under section 1928 of the Social Security Act, as enacted by section 13631 of Pub. L. 103–66. This section provides for the establishment of a program to distribute free vaccines to all vaccine-eligible children, as defined by this section. The rule modifies the existing Vaccine Injury Table, a mechanism by which compensation is awarded to individuals who have been found to have suffered from vaccine-related injuries. Because the two authorities are not related, the publication of this rule should not have any impact on the Vaccines for Children Program.

Paperwork Reduction Act of 1980

This final rule has no information collection requirements.

List of Subjects in 42 CFR Part 100

Biologics, Health insurance, and Immunization.

Dated: September 23, 1996.

Ciro V. Sumaya,

Administrator, Health Resources and Services Administration.

Approved: November 22, 1996.

Donna E. Shalala,

Secretary.

Accordingly, 42 CFR part 100 is amended as set forth below.

PART 100—VACCINE INJURY COMPENSATION

1. The authority citation for part 100 is revised to read as follows:

Authority: Sec. 215 of the Public Health Service Act (42 U.S.C. 216); sec. 2115 of the PHS Act, 100 Stat. 3767, as revised (42 U.S.C. 300aa–15); § 100.3, Vaccine Injury Table, issued under secs. 312 and 313 of Pub. L. 99–660, 100 Stat. 3779—3782 (42 U.S.C. 300aa–

1 note) and sec. 2114(c) and (e) of the PHS Act, 100 Stat. 3766 and 107 Stat. 645 (42 U.S.C. 300aa–14(c) and (e)).

2. Section 100.3 is amended by revising the Vaccine Injury Table in paragraph (a); by republishing the introductory text in paragraph (b); by revising paragraph (b)(2)(i); by revising paragraph (b)(6); by adding paragraphs (b)(7), (b)(8), (b)(9), (b)(10), and (b)(11); and by revising paragraph (c) to read as follows:

§ 100.3 Vaccine injury table.

(a) * * *

VACCINE INJURY TABLE

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT).	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Brachial Neuritis	2–28 days.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, DTaP, P, DTP–Hib).	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Encephalopathy (or encephalitis)	72 hours.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
III. Measles, mumps, and rubella vaccine or any of its components (e.g., MMR, MR, M, R).	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Encephalopathy (or encephalitis)	5–15 days (not less than 5 days and not more than 15 days).
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
IV. Vaccines containing rubella virus (e.g., MMR, MR, R).	A. Chronic arthritis	7–42 days.
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
V. Vaccines containing measles virus (e.g., MMR, MR, M).	A. Thrombocytopenic purpura	7–30 days.
	B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient.	6 months.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
VI. Vaccines containing polio live virus (OPV)	A. Paralytic Polio	
	—in a non-immunodeficient recipient	30 days.
	—in an immunodeficient recipient	6 months.
	—in a vaccine associated community case	Not applicable.
	B. Vaccine-Strain Polio Viral Infection	
	—in a non-immunodeficient recipient	30 days.
	—in an immunodeficient recipient	6 months.
	—in a vaccine associated community case	Not applicable.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
VII. Vaccines containing polio inactivated virus (e.g., IPV).	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Any acute complication or sequela (including death of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed..	Not applicable.
VIII. Hepatitis B. vaccines	A. Anaphylaxis or anaphylactic shock	4 hours.

VACCINE INJURY TABLE—Continued

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
IX. Hemophilus influenzae type b polysaccharide vaccines (unconjugated, PRP vaccines).	A. Early-onset Hib disease	7 days.
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.	Not applicable.
X. Hemophilus influenzae type b polysaccharide conjugate vaccines.	No Condition Specified	Not applicable.
XI. Varicella vaccine	No Condition Specified	Not applicable.
XII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage.	No Condition Specified	Not applicable.

(b) *Qualifications and aids to interpretation.* The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table to paragraph (a) of this section:

* * * * *

(2) * * *

(i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).

* * * * *

(6) *Chronic Arthritis.* (i) For purposes of paragraph (a) of this section, chronic arthritis may be found in a person with no history in the 3 years prior to vaccination of arthropathy (joint disease) on the basis of:

(A) Medical documentation, recorded within 30 days after the onset, of objective signs of acute arthritis (joint swelling) that occurred between 7 and 42 days after a rubella vaccination;

(B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination; and

(C) Medical documentation of an antibody response to the rubella virus.

(ii) For purposes of paragraph (a) of this section, the following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/determatomyositis, fibromyalgia, necrotizing vascultitis and vasculopathies and Sjogren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction) metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reiter's syndrome, or blood disorders.

(iii) Arthralgia (joint pain) or stiffness without joint swelling shall not be viewed as chronic arthritis for purposes of paragraph (a) of this section.

(7) *Brachial neuritis.* (i) This term is defined as dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, divisions, or cords) without involvement of other peripheral (e.g., nerve roots or a single peripheral nerve) or central (e.g., spinal cord) nervous system structures. A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is followed in days or weeks by weakness and atrophy in upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. The neuritis, or plexopathy, may be present on the same side as or the opposite side of the injection; it is sometimes bilateral, affecting both upper extremities.

(ii) Weakness is required before the diagnosis can be made. Motor, sensory, and reflex findings on physical examination and the results of nerve conduction and electromyographic studies must be consistent in confirming that dysfunction is attributable to the brachial plexus. The condition should thereby be distinguishable from conditions that may give rise to dysfunction of nerve roots (i.e., radiculopathies) and peripheral nerves (i.e., including multiple monoeuropathies), as well as other peripheral and central nervous system structures (e.g., cranial neuropathies and myelopathies).

(8) *Thrombocytopenic purpura.* This term is defined by a serum platelet count less than 50,000/mm^3. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with other causes such as hypersplenism, autoimmune disorders (including alloantibodies from previous transfusions) myelodysplasias, lymphoproliferative disorders, congenital thrombocytopenia or hemolytic uremic syndrome. This does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura (ITP) that are mediated, for example, by viral or fungal infections, toxins or drugs. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with disseminated intravascular coagulation, as observed with bacterial and viral infections. Viral infections include, for example, those infections secondary to Epstein Barr virus, cytomegalovirus, hepatitis A and B, rhinovirus, human immunodeficiency virus (HIV), adenovirus, and dengue virus. An antecedent viral infection may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing. Bone marrow examination, if performed, must reveal a normal or an increased number of megakaryocytes in an otherwise normal marrow.

(9) *Vaccine-strain measles viral infection.* This term is defined as a disease caused by the vaccine-strain that should be determined by vaccine-specific monoclonal antibody or polymerase chain reaction tests.

(10) *Vaccine-strain polio viral infection.* This term is defined as a disease caused by poliovirus that is isolated from the affected tissue and should be determined to be the vaccine-strain by oligonucleotide or polymerase chain reaction. Isolation of poliovirus from the stoll is not sufficient to establish a tissue specific infection or disease caused by vaccine-strain poliovirus.

(11) *Early-onset Hib disease.* This term is defined as invasive bacterial illness associated with the presence of Hib organism on culture of normally sterile body fluids or tissue, or clinical findings consistent with the diagnosis of epiglottitis. Hib pneumonia qualifies as invasive Hib disease when radiographic findings consistent with the diagnosis of pneumonitis are accompanied by a blood culture positive for the Hib organism. Otitis media, in the absence of the above findings, does not qualify as invasive bacterial disease. A child is considered to have suffered this injury only if the vaccine was the first Hib immunization received by the child.

(c) *Effective date provisions.* (1) Except as provided in paragraph (c)(2) of this section, the revised Table of Injuries set forth in paragraph (a) of this section and the Qualifications and Aids to Interpretation set forth in paragraph (b) of this section apply to petitions for compensation under the Program filed with the United States Court of Federal Claims on or after March 24, 1997. Petitions for compensation filed before such date shall be governed by section 2114(a) and (b) of the Public Health Service Act as in effect on January 1, 1995, or by § 100.3 as in effect on March 10, 1995 (see 60 FR 7678, *et seq.*, February 8, 1995), as applicable.

(2) The inclusion of hepatitis B, Hib, and varicella vaccines and other new vaccines (Items VIII, IX, X, XI and XII of the Table) will be effective on the effective date of a tax enacted to provide funds for compensation paid with respect to such vaccines. A notice will be published in the Federal Register to announce the effective date of such a tax.

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BILLING CODE 4160–15–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Chapter I

[CC Docket No. 96–152; FCC 97–35]

Implementation of the Telecommunications Act of 1996: Telemessaging, Electronic Publishing, and Alarm Monitoring Services

AGENCY: Federal Communications Commission.

ACTION: Final rule; Clarification and interpretation.

SUMMARY: The First Report and Order (Order), released February 7, 1997, implements the non-accounting requirements prescribed by Congress in sections 260 and 274 of the Telecommunications Act of 1996 (the Act), which respectively govern the provision of telemessaging and electronic publishing services. The Order promotes the pro-competitive and deregulatory objectives of the Act.

EFFECTIVE DATE: March 24, 1997. The information collections in this Order will not become effective until at least May 1, 1997.

FOR FURTHER INFORMATION CONTACT: Lisa Sockett, Attorney, Common Carrier Bureau, Policy and Program Planning Division, (202) 418–1580. For additional information concerning the information collections contained in this Order contact Dorothy Conway at (202) 418–0217, or via the Internet at dconway@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order adopted February 6, 1997, and released February 7, 1997. The full text of this Order is available for inspection and copying during normal business hours in the FCC Reference Center, 1919 M St., NW., Room 239, Washington, DC. The complete text also may be obtained through the World Wide Web, at http://www.fcc.gov/Bureaus/Common Carrier/Orders/fcc9735.wp, or may be purchased from the Commission's copy contractor, International Transcription Service, Inc., (202) 857–3800, 2100 M St., NW., Suite 140, Washington, DC 20037.

This Order contains new or modified information collections subject to the Paperwork Reduction Act of 1995 (PRA). It has been submitted to the Office of Management and Budget (OMB) for review under the PRA. OMB, the general public, and other federal agencies are invited to comment on the proposed or modified information collections contained in this proceeding.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act, the Order contains a Final Regulatory Flexibility Certification which is set forth in the Order. A brief description of the certification follows.

The Commission certifies, pursuant to 5 U.S.C. 605(b), that the clarification and interpretation adopted in this Order will not have a significant economic impact on a substantial number of ''small entities,'' as this term is defined in 5 U.S.C. 601(6). The Commission therefore is not required to prepare a final regulatory flexibility analysis of the clarification and interpretation adopted in this Order. This certification and a statement of its factual basis are set forth in the Order, as required by 5 U.S.C. 605(b).

Paperwork Reduction Act

This Order contains either a new or modified information collection. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and OMB to comment on the information collections contained in this Order, as required by the Paperwork Reduction Act of 1995, Public Law No. 104–12. Written comments by the public on the information collections are due March 24, 1997. OMB notification of action is due April 21, 1997. Comments should address: (a) Whether the new or modified collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents including the use of automated collection techniques or other forms of information technology.

OMB Approval Number: 3060–0738

Title: Implementation of the Telecommunications Act of 1996: Telemessaging, Electronic Publishing, and Alarm Monitoring Services, CC Docket No. 96–152.

Form No.: N/A.

Type of Review: Revision.

Respondents: Business or other for profit.

Public reporting burden for the collection of information is estimated as follows: