



DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

RIN 0906-AB24

National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table; Notice of Proposed Rulemaking; Public Comment Period; Delay of Effective Date

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking; proposed delay of effective date; request for comments.

SUMMARY: In accordance with the Presidential directive as expressed in the memorandum of January 20, 2021, from the Assistant to the President and Chief of Staff, entitled “Regulatory Freeze Pending Review,” this action proposes, following a brief public comment period, to further delay until April 23, 2021, the effective date of the rule entitled “National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table,” published in the Federal Register on January 21, 2021. That final rule is scheduled to take effect on February 22, 2021. HHS seeks comments on this proposed delay, which would allow it additional opportunity for review and consideration of the new rule.

DATES: Written comments and related material to this proposed rule must be received to the online docket via <https://www.regulations.gov> on or before February 16, 2021.

ADDRESSES: You may submit written comments electronically by the following method:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions on the website for submitting comments.

Instructions. Include the HHS Docket No. HRSA-2021-0001 in your comments. All comments received will be posted without change to <http://www.regulations.gov>. Please do not include any personally identifiable or confidential business information you do not want publicly disclosed.

FOR FURTHER INFORMATION CONTACT: Please visit the National Vaccine Injury Compensation Program's website, <https://www.hrsa.gov/vaccinecompensation/>, or contact Tamara Overby, Acting Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, Room 08N146B, 5600 Fishers Lane, Rockville, MD 20857; by email at vaccinecompensation@hrsa.gov; or by telephone at (855) 266-2427.

SUPPLEMENTARY INFORMATION: HHS published a notice of proposed rulemaking on July 20, 2020 (85 FR 43794), and final rule on January 21, 2021 (86 FR 6249). That final rule amended the provisions of 42 CFR 100.3 by removing Shoulder Injury Related to Vaccine Administration, vasovagal syncope, and Item XVII from the Vaccine Injury Table. The January 20, 2021, memorandum from the Assistant to the President and Chief of Staff, entitled “Regulatory Freeze Pending Review,” instructed federal agencies to consider delaying the effective date of rules published in the Federal Register, but which have not yet taken effect, for a period of 60 days so that the new Administration may review recently published rules for “any questions of fact, law, and policy the rule may raise.” The memorandum notes certain exceptions that do not apply here. On January 20, 2021, the Office of Management and Budget (OMB) also published OMB Memorandum M-21-14, Implementation of Memorandum Concerning Regulatory Freeze Pending Review, which provides guidance regarding the Regulatory Freeze Memorandum. See OMB M-21-14, Implementation of Memorandum Concerning Regulatory Freeze Pending Review, <https://www.whitehouse.gov/wp-content/uploads/2021/01/M-21-14-Regulatory-Review.pdf>. OMB M-21-14 explains that pursuant to the Regulatory Freeze Memorandum, agencies “should consider postponing the effective dates for 60 days and reopening the rulemaking process” for “rules that have not yet taken effect and about which questions involving law, fact, or policy have been raised.” *Id.* In accordance with the Regulatory Freeze Memorandum and OMB M-21-14, HHS proposes to delay the effective date of the final rule revising the Vaccine Injury Table to April 23, 2021, which would be 60 days beyond its original effective date. HHS needs to extend the effective

date of the underlying rule by 60 days to determine whether its promulgation raises any legal issues, including but not limited to (1) whether the Advisory Commission on Childhood Vaccines was properly notified of the proposed rule pursuant to 42 USC 300aa-14(c), and (2) whether the public was properly notified of the entire revised regulation, 42 CFR 100.3(b)–(e) (including the qualifications and aids to interpretation and the coverage provisions), given that both the proposed and final rules published in the Federal Register included only the revised Vaccine Injury Table itself, but not the entire revised regulation. HHS believes that the proposed delay is reasonable, would allow HHS time to receive public comments, and would not be disruptive since the underlying rule has not yet taken effect and the agency has not yet implemented the rule.

HHS seeks comment on the proposed delay, including the proposed delay’s impact on any legal, factual, or policy issues raised by the underlying rule and whether further review of those issues warrants such a delay. All other comments on the underlying rule will be considered to be outside the scope of this rulemaking. HHS therefore seeks comment by February 16, 2021 on its proposal to extend the effective date by 60 days to April 23, 2021.

Norris Cochran,

Acting Secretary,

Department of Health and Human Services.