claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Janet Norden, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1127.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of November 15, 2018 (83 FR 57378), FDA published a proposed rule with a 60-day comment period to implement the statutory changes made to the Federal Food, Drug, and Cosmetic Act by section 3024 of the 21st Century Cures Act (Pub. L. 114–255) to allow for a waiver or alteration of informed consent when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects. The proposed rule, if finalized, would permit an institutional review board (IRB) to waive or alter certain informed consent elements or to waive the requirement to obtain informed consent, under limited conditions, for certain minimal risk clinical investigations. Comments on the proposed rule will inform FDA's rulemaking to establish regulations for IRB waiver or alteration of informed consent for certain minimal risk clinical investigations.

The Agency received a request for a 60-day extension of the comment period for the proposed rule. This request conveyed concern that the 60-day comment period did not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule. FDA considered the request and in the **Federal Register** of December 20, 2018 (83 FR 65322), the Agency extended the comment period for the proposed rule for 30 days, until February 13, 2019. The Agency believed that a 30-day extension allowed adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

On February 13, 2019, the date that the comment period closed for the proposed rule, the Federal eRulemaking Portal (*https://www.regulations.gov*) was unavailable to receive public comments from 5:35 p.m. until 7:40 a.m. on February 14, 2019. The Agency is aware that interested persons attempted to submit comments during the period of time that *https://www.regulations.gov* was unavailable. Therefore, FDA is reopening the comment period for the proposed rule for 10 days, until March 7, 2019 to allow additional time for interested persons to submit comments.

Dated: February 20, 2019.

**Lowell J. Schiller,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 2019–03195 Filed 2–22–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### 26 CFR Part 54

## DEPARTMENT OF LABOR

### Employee Benefits Security Administration

### 29 CFR Part 2590

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 45 CFR Parts 144, 146, and 147

**[CMS–9923–NC]**

## Request for Information Regarding Grandfathered Group Health Plans and Grandfathered Group Health Insurance Coverage

**AGENCY:** Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

**ACTION:** Request for information.

**SUMMARY:** This document is a request for information regarding grandfathered group health plans and grandfathered group health insurance coverage. Given the limited information available regarding such coverage, the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services (the Departments) are issuing this request for information to gather input from the public in order to better understand the challenges that group health plans and group health insurance issuers face in avoiding a loss of grandfathered status, and to determine whether there are opportunities for the Departments to assist such plans and issuers, consistent with the law, in preserving the grandfathered status of group health plans and group health insurance coverage in ways that would benefit employers, employee organizations, plan participants and beneficiaries, and other stakeholders.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 27, 2019.

**ADDRESSES:** Written comments may be submitted to the addresses specified below. Any comment that is submitted will be shared among the Departments. Please do not submit duplicates.

All comments will be made available to the public. *Warning:* Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the internet exactly as received and can be retrieved by most internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

In commenting, refer to file code CMS–9923–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention:

CMS–9923–NC, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9923–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** William Fischer, Internal Revenue Service, Department of the Treasury, at (202) 317–5500.

Matthew Litton or David Sydlik, Employee Benefits Security Administration, Department of Labor, at (202) 693–8335.

Kiahana Brooks, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (301) 492–4400.

*Customer Service Information:* Individuals interested in obtaining information from the Department of Labor (DOL) concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the DOL's website (*www.dol.gov/ebsa*). In addition, information from the Department of Health and Human Services (HHS) on private health insurance coverage and on nonfederal governmental group health plans can be found on the Centers for Medicare & Medicaid Services (CMS) website (*www.cms.gov/cciio*), and information on health care reform can be found at *www.HealthCare.gov*.

**SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. Comments received before the close of the comment period are posted on the following website as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that website to view public comments.

## I. Background

### *A. Purpose*

On January 20, 2017, the President issued Executive Order 13765, ''Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal,'' (82 FR 8351) ''to minimize the unwarranted economic and regulatory burdens of the [Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively, PPACA), as amended].'' To meet these objectives, the President directed that the executive departments and agencies with authorities and responsibilities under PPACA, ''to the maximum extent permitted by law . . . shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of [PPACA] that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.''

The Departments share interpretive jurisdiction over section 1251 of PPACA, which, as described in more detail in section I.B of this document, generally provides that certain group health plans and health insurance coverage existing as of March 23, 2010, the date of enactment of PPACA, (that is, grandfathered health plans) are subject to only certain provisions of PPACA. Consistent with the objectives of Executive Order 13765, the Departments are issuing this request for information to gather input from the public in order to better understand the challenges that group health plans and group health insurance issuers face in avoiding a loss of grandfathered status and to determine whether there are opportunities for the Departments to assist such plans and issuers, consistent with the law, in preserving the grandfathered status of group health plans and group health insurance coverage in ways that would benefit employers, employee organizations, plan participants and beneficiaries, and other stakeholders.

### *B. Grandfathered Group Health Plans and Grandfathered Group Health Insurance Coverage*

Section 1251 of PPACA provides that grandfathered health plans are subject to only certain provisions of PPACA, for as long as they maintain their status as grandfathered health plans.[1] For example, grandfathered health plans are neither subject to the requirement to cover certain preventive services without cost sharing under section 2713 of the PHS Act, enacted by section 1001 of PPACA, nor the annual limitation on cost sharing set forth under section 1302(c) of PPACA and section 2707(b) of the PHS Act, enacted by section 1201 of PPACA.

On June 17, 2010, the Departments issued interim final rules with request for comments implementing section 1251 of PPACA (75 FR 34538). On November 17, 2010, the Departments issued an amendment to the interim final rules with request for comments to permit certain changes in policies, certificates, or contracts of insurance without loss of grandfathered status (75 FR 70114). Also, over the course of 2010 and 2011, the Departments released Affordable Care Act Implementation Frequently Asked Questions (FAQs) Parts I, II, IV, V, and VI to answer questions related to maintaining a plan's status as a grandfathered health plan.[2] After consideration of the comments and feedback received from stakeholders, the Departments issued regulations on November 18, 2015 (80 FR 72192) (November 2015 final rules) that finalized the interim final rules without substantial change and incorporated the clarifications that the Departments had previously provided in other guidance.

In general, under the November 2015 final rules,[3] a group health plan or group health insurance coverage is considered grandfathered if it has

[1] For a list of the market requirement provisions under title XXVII of the Public Health Service Act (PHS Act), as added or amended by PPACA, and incorporated into the Employee Retirement Income Security Act of 1974 and the Internal Revenue Code of 1986, applicable to grandfathered health plans, visit *https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/grandfathered-health-plans-provisions-summary-chart.pdf*.

[2] *See* Affordable Care Act Implementation FAQs Part I, available at *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-i.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs.html*; Affordable Care Act Implementation FAQs Part II, available at *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-ii.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html*; Affordable Care Act Implementation FAQs Part IV, available at *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-iv.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs4.html*; Affordable Care Act Implementation FAQs Part V, available at *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-v.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html*; and Affordable Care Act Implementation FAQs Part VI, available at *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-vi.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs6.html*.

[3] *See* 26 CFR 54.9815–1251, 29 CFR 2590.715–1251, and 45 CFR 147.140.

continuously provided coverage for someone (not necessarily the same person, but at all times at least one person) since March 23, 2010, and if it has not ceased to be a grandfathered plan due to certain actions taken by the plan (or its sponsor) or issuer.

The November 2015 final rules specify when changes to the terms of a plan or coverage cause the plan or coverage to cease to be a grandfathered health plan. Specifically, the regulations outline certain changes to benefits, cost-sharing requirements, and contribution rates that will cause a plan or coverage to relinquish its grandfathered status. The November 2015 final rules state that such changes will cause a plan or coverage to cease to be a grandfathered plan when the changes become effective, regardless of when such changes are adopted. In addition, the November 2015 final rules require that a plan or coverage include a statement that it believes the plan or coverage is a grandfathered health plan, as well as provide contact information for questions and complaints, in any summary of benefits provided under the plan.

The November 2015 final rules further provide that, once grandfathered status is relinquished, there is no opportunity to cure the loss of grandfathered status. Although the Departments are interested in ways to assist grandfathered group health plans and grandfathered group health insurance coverage in maintaining their grandfathered status, in the Departments' view, there is no authority for non-grandfathered plans to become grandfathered.

Under the November 2015 final rules, certain changes to a group health plan or coverage will not result in a loss of grandfathered status. For example, new employees and their beneficiaries may enroll in a group health plan or group health insurance coverage without causing a loss of grandfathered status. Further, the addition of a new contributing employer or a new group of employees of an existing contributing employer to a grandfathered multiemployer health plan will not affect the plan's grandfathered status. Also, grandfathered status is determined separately for each benefit package under a group health plan or coverage; thus, if any benefit package under the plan or coverage loses its grandfathered status, it will not affect the grandfathered status of the other benefit packages.

It is the Departments' understanding that the number of group health plans and group health insurance policies that are considered to be grandfathered has declined each year since the enactment of PPACA, but many employers continue to maintain group health plans and coverage that have retained grandfathered status. The Kaiser Family Foundation's annual Employer Health Benefits Survey estimates that approximately 20 percent of employers that offered health benefits to their employees offered at least one grandfathered group health plan in 2018, a decrease from 72 percent in 2011.[4] The same study also estimates that 16 percent of American workers with employer-sponsored coverage were enrolled in a grandfathered group health plan in 2018, a decrease from 56 percent in 2011. If these estimates are correct, the fact that a significant number of grandfathered group health plans remain indicates that some employers and issuers have found value in preserving grandfathered status, and that some consumers, when given the choice between grandfathered and non-grandfathered employer plans, have found value in choosing to remain in their grandfathered group health plans and coverage.

With respect to the individual market, it is the Departments' understanding that the number of individuals with grandfathered individual health insurance coverage has declined each year since PPACA was enacted and only a small number of individuals are currently enrolled in grandfathered individual health insurance coverage.[5] Further, grandfathered coverage may not be sold in the individual market to new policyholders. For these reasons, this request for information focuses on grandfathered group health plan and grandfathered group health insurance coverage, and does not address grandfathered individual health insurance coverage.

## II. Solicitation of Comments

The Departments are requesting comments to contribute to the Departments' understanding of the issues related to grandfathered health plans, and to estimate the impact of any potential changes to the rules for retention of grandfathered status for group health plans and group health insurance coverage, both generally and with respect to the following specific areas:

### *A. Maintaining (or Relinquishing) Grandfathered Status*

1. What actions could the Departments take, consistent with the law, to assist group health plan sponsors and group health insurance issuers preserve the grandfathered status of a group health plan or coverage?

2. What challenges do group health plan sponsors and group health insurance issuers face regarding retaining the grandfathered status of a plan or coverage? Does any particular requirement(s) for maintaining grandfathered status create more challenges than others, and if so, how could the requirement(s) be modified to reduce such challenges?

3. For group health plan sponsors and group health insurance issuers that have chosen to preserve grandfathered status of their plans or coverage, what are the primary reasons for doing so? If grandfathered status is preserved so that particular PPACA requirements will not apply to the plan, please specify the particular PPACA requirements not included in the grandfathered plan and explain any related concerns.

4. What are the reasons why participants and beneficiaries have remained enrolled in grandfathered group health plans if alternatives are available?

5. What are the costs, benefits, and other factors considered by plan sponsors and health insurance issuers when considering whether to retain grandfathered status of their plans or coverage?

6. Is preserving grandfathered status important to group health plan participants and beneficiaries? If so, which participants and beneficiaries benefit the most and which, if any, are affected detrimentally by the employer offering grandfathered group health plan coverage?

7. What is the typical change in benefits, employer contributions or employee organization contributions, and cost-sharing requirements that causes a grandfathered group health plan or grandfathered group health insurance coverage to lose its grandfathered status?

8. Do the grandfathered health plan disclosure requirements in the November 2015 final rules provide adequate, useful, and timely information to plan participants and

[4] 2018 Employer Health Benefits Survey, Kaiser Family Foundation, available at *https://www.kff.org/report-section/2018-employer-health-benefits-survey-section-13-grandfathered-health-plans/*. *See also* 2011 Employer Health Benefits Survey, Kaiser Family Foundation, available at: *https://kaiserfamilyfoundation.files.wordpress.com/2013/04/8225.pdf*; and Kaiser Health News FAQ: Grandfathered Health Plans at: *http://khn.org/news/grandfathered-plans-faq/*. Also, the Agency for Healthcare Research and Quality, Center for Financing, Access and Cost Trends reports that 22.1 percent of employees were enrolled in grandfathered health plans in 2017 according to 2017 Medical Expenditure Panel Survey-Insurance Component (MEPS–IC) data. The related MEPS–IC survey is available at: *https://meps.ahrq.gov/survey_comp/ic_survey/2017/meps10.s.htm*.

[5] *See* 83 FR 54420, 54429 (Oct. 29, 2018).

beneficiaries regarding grandfathered status? If not, how could the disclosure be improved?

*B. General Information About Grandfathered Group Health Plans and Group Health Insurance Coverage*

1. Other than the Kaiser Family Foundation's ''Employer Health Benefits Annual Survey,'' and the MEPS–IC survey, what data resources are available to help the Departments better understand how many group health plans and group health insurance policies are considered grandfathered and how many participants and beneficiaries are enrolled in such plans and coverage?

2. What are the characteristics (for example, plan size, geographic areas, or industries) of grandfathered group health plans and the plan sponsors and group health insurance issuers that have chosen to retain the grandfathered status of their plans or coverage? Do grandfathered group health plans or the plan sponsors and group health insurance issuers that have chosen to retain the grandfathered status of their plans or coverage share common characteristics?

3. Do group health plan sponsors and group health insurance issuers that have chosen to retain grandfathered status for certain plans, benefit packages, or policies also offer other plans, benefit packages, or policies that are not grandfathered? If so, why?

4. What are the typical differences in benefits, cost-sharing, and premiums (including employer contributions, employee organization contributions, and employee contributions) associated with grandfathered group health plans and grandfathered group health insurance coverage compared to non-grandfathered group health plans?

5. How many group health plan sponsors and group health insurance issuers are considering making changes to their plans or coverage over the next few years that are likely to cause loss of grandfathered status under the November 2015 final rules? How many individuals would be affected?

6. What impact do grandfathered group health plans and grandfathered group health insurance coverage have on the individual and small group market risk pools?

## III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. However, section II of this document does contain a general solicitation of comments in the form of a request for information. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA. Consequently, there is no need for review by the Office of Management and Budget under the authority of the PRA.

Signed at Washington, DC, this 13th day of February 2019.

**Victoria Judson,**

*Associate Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes), Internal Revenue Service, Department of the Treasury.*

Signed at Washington, DC, this 19th day of February, 2019.

**Carol Weiser,**

*Acting Benefits Tax Counsel, Department of the Treasury.*

Signed at Washington, DC, this 13th day of February 2019.

**Preston Rutledge,**

*Assistant Secretary, Employee Benefits Security Administration, Department of Labor.*

Dated: February 13, 2019.

**Seema Verma,**

*Administrator, Centers for Medicare & Medicaid Services.*

Dated: February 13, 2019.

**Alex M. Azar II,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2019–03170 Filed 2–21–19; 4:15 pm]

**BILLING CODE 4510–29–P; 4830–01–P; 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### 42 CFR Part 88

**[NIOSH Docket 094]**

## World Trade Center Health Program; Petition 020—Stroke; Finding of Insufficient Evidence

**AGENCY:** Centers for Disease Control and Prevention, HHS.

**ACTION:** Denial of petition for addition of a health condition.

**SUMMARY:** On August 26, 2018, the Administrator of the World Trade Center (WTC) Health Program received a petition (Petition 020) to add ''two forms of stroke, both ischemic and non-aneurysmal hemorrhagic,'' to the List of WTC-Related Health Conditions (List). Upon reviewing the scientific and medical literature, including information provided by the petitioner, the Administrator has determined that the available evidence does not have the potential to provide a basis for a decision on whether to add stroke to the List. The Administrator also finds that insufficient evidence exists to request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee (STAC), to publish a proposed rule, or to publish a determination not to publish a proposed rule.

**DATES:** The Administrator of the WTC Health Program is denying this petition for the addition of a health condition as of February 25, 2019.

**ADDRESSES:** Visit the WTC Health Program website at *https://www.cdc.gov/wtc/received.html* to review Petition 020.

**FOR FURTHER INFORMATION CONTACT:** Rachel Weiss, Program Analyst, 1090 Tusculum Avenue, MS: C–48, Cincinnati, OH 45226; telephone (855) 818–1629 (this is a toll-free number); email *NIOSHregs@cdc.gov.*

**SUPPLEMENTARY INFORMATION:**

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### A. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111–347, as amended by Pub. L. 114–113), added Title XXXIII to the Public Health Service (PHS) Act,[1] establishing the WTC Health Program within the Department of Health and

[1] Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm–61. Those portions of the James Zadroga 9/11 Health and Compensation Act of 2010 found in Titles II and III of Public Law 111–347 do not pertain to the WTC Health Program and are codified elsewhere.