

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 154

[CMS-9999-FC]

RIN 0938-AQ68

Rate Increase Disclosure and Review

AGENCY: Center for Consumer Information and Insurance Oversight, Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period implements requirements for health insurance issuers regarding disclosure and review of unreasonable premium increases under section 2794 of the Public Health Service Act. The final rule establishes a rate review program to ensure that all rate increases that meet or exceed a specified threshold are reviewed by a State or CMS to determine whether they are unreasonable and that certain rate information be made public.

DATES: *Effective date.* This rule is effective on July 18, 2011.

Comment date. We will consider comments on § 154.102 regarding the definitions of “individual market” and “small group market” that are received at one of the addresses provided in the **ADDRESSES** section of this rule no later than 5 p.m. EST on July 18, 2011.

ADDRESSES: In commenting please refer to file code CMS-9999-FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four 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 instructions under the “More Search Options” tab.

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-9999-FC, P.O. Box 8010, Baltimore, MD 21244-8010.

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-9999-FC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments only to the following addresses prior to the close of comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

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. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, phone (800) 743-3591.

FOR FURTHER INFORMATION CONTACT: Sally McCarty, (301) 492-4489 (or by e-mail: ratereview@hhs.gov).

SUPPLEMENTARY INFORMATION: *Comment Subject Areas:* We will consider comments on how individual and small

group coverage sold through associations should be treated under the rate review process as discussed in this final rule with comment period that are received by the date and time indicated in the **DATES** section of this final rule with comment period.

I. Background

The Patient Protection and Affordable Care Act (Pub. L. 111-148) was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (Pub. L. 111-152) was enacted on March 30, 2010. In this preamble, we refer to the two statutes collectively as the Affordable Care Act. The Affordable Care Act reorganizes, amends, and adds to the provisions of Part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets.

Section 1003 of the Affordable Care Act adds a new section 2794 of the PHS Act which directs the Secretary of the Department of Health and Human Services (the Secretary), in conjunction with the States, to establish a process for the annual review of “unreasonable increases in premiums for health insurance coverage.” The statute provides that this process shall require health insurance issuers to submit to the Secretary and the applicable State justifications for unreasonable premium increases prior to the implementation of the increases.

On December 23, 2010, we published a proposed rule entitled “Rate Increase Disclosure and Review.” Sixty comments were received by the end of the comment period. Commenters included several State insurance regulators; the National Association of Insurance Commissioners (“NAIC”); many consumer, retiree, and patient organizations; health care providers; health insurance issuers and related trade associations (collectively, “industry”); an organization representing the actuarial profession; and others.

II. Provisions of the Proposed Rule and Responses to Comments

In this section of the preamble, we summarize each section of the proposed rule, discuss the public comments received on each section (if any), and provide responses to the comments.

A. Subpart A—General Provisions

1. Basis and Scope (§ 154.101)

Section 154.101 of the proposed rule indicated that this rule would implement section 2794 of the PHS Act. Specifically, the rule would establish

disclosure requirements on health insurance issuers offering health insurance coverage in the small group or individual markets concerning rate increases that are above a specific threshold and designated as subject to review. The rule proposed to establish the process by which such increases are reviewed to determine whether they are unreasonable.

Comment: One consumer commenter expressed concern that the proposed rule did not include authority for CMS to require an issuer to rescind an unreasonable rate or otherwise impose penalties on such issuer for proposing an unreasonable rate.

Response: Section 2794 of the PHS Act only provides CMS with the authority to require justification and disclosure of proposed rate increases. However, if an issuer fails to comply with the requirements set forth in this final rule, CMS could seek a court order against the issuer to enforce compliance.

Some States have the authority to deny proposed rate increases, and the grants awarded under section 2794(b) of the PHS Act provided supplemental performance funding for States that have or seek such authority. In addition, States receiving grants under section 2794(b) of the PHS Act will be required to make recommendations to State Exchanges regarding whether issuers should be excluded from participation in the Exchanges based on patterns or practices of excessive or unjustified premium increases. Section 1311(e)(2) of the Affordable Care Act requires Exchanges to take the States' recommendations into consideration when determining whether to make health plans available through the Exchanges.

2. Definitions (§ 154.102)

Certain key definitions in § 154.102 of the proposed rule are discussed below.

a. Individual Market and Small Group Market. The proposed rule would have defined "individual market" and "small group market" as they are defined under the applicable State rate filing laws, if the State laws included such definitions. Under the proposed rule, if a State rate filing law did not include definitions for the individual market or the small group market, the definitions under the PHS Act would be used, with the exception that a small group would be defined to include employers with 50 or fewer employees.

Comment: State regulators, industry, and other commenters agreed that CMS generally should defer to State rate filing laws concerning the definitions for the individual market and the small group market. One State regulator

commenter requested clarification as to whether short-term limited duration coverage was required to be included in the proposed rule's definition of individual market, if the State excluded such coverage from its own definition.

Response: The final rule continues to defer to State rate filing law definitions for individual market and small group market including in cases in which the State definition of individual market excludes short-term limited duration coverage. This rule, therefore, does not require that a State with an Effective Rate Review Program review proposed rate increases for short-term limited duration coverage if the State's rate filing law does not consider short-term limited duration coverage to be individual market coverage.

Comment: Five commenters specifically expressed concern that the proposed rule, as drafted, would not cover association coverage sold to individuals and small employers in some States and recommended that the final rule include them in its scope.

One State regulator commented that a large percentage of small employers purchase health insurance coverage through associations in her State. Under that State's law, small employers purchasing through an association are considered one large group not subject to the provisions of State law that apply to small group coverage. However, the commenter noted that rate increases are based on each small employer's own experience, and not that of the entire association, so that rate-setting for association coverage sold to small groups is not the same as that for large employer coverage. She recommended that association coverage be treated consistently for purposes of section 2794 of the PHS Act and other PHS Act provisions. As CMS Insurance Standards Bulletin Transmittal Nos. 02-02 and 02-03 makes clear, PHS Act requirements generally apply to individual market and small group market coverage sold through associations in the same manner as they apply to other individual market and small group market coverage sold directly to consumers and small employers.

Another State regulator voiced similar concerns, noting that his State had more small employers with association coverage than small employers with coverage in the traditional small group market. This State regulator urged that the final rule categorize individual and small employer coverage based on the purchasers of such coverage.

A major trade association representing issuers found the proposed rule ambiguous concerning the regulation of

product filings in the individual and small group markets offered through out-of-state associations and group trusts. The commenter noted that in some cases, a group policy is issued in one State, with certificates being issued to individuals or small groups in other States. Since many States only review rates for policies issued in their States, their rate review laws would not apply to coverage sold through out-of-state associations and group trusts.

Similarly, one large issuer noted that CMS's deference to State rate filing law definitions could result in some individual market products sold through associations and group trusts not receiving any review by States or CMS. This commenter recommended that consistent filing requirements and rate review standards be applied to all products marketed to individuals, regardless of the technical insurance arrangement that might be involved, and that CMS review rates for individual market products sold through associations and group trusts in cases where States did not. The commenter thought this approach would ensure uniform consumer protection and advance competition by subjecting all issuers to the same rules.

Lastly, one consumer commenter stated that all coverage marketed to individuals and small employers should be subject to the same review, regardless of whether the coverage was marketed directly to consumers or through associations.

Response: Given the fact that we did not include a discussion on the association health plan issue in the proposed rule, we are not making a determination regarding this issue in this final rule, but instead are seeking comments and additional data on the definitions of "individual market" and "small group market" in § 154.102 of this final rule in relation to whether to provide that individual and small employer policies sold through associations are to be included in the rate review process, even if the State excludes such coverage from its definitions of individual and small group market coverage. Given the comments received and our policy goals with regard to rate review, we are inclined to amend the definitions of individual market and small group market in § 154.102 to include coverage sold to individuals and small groups through associations in all cases. However, as indicated above, we are interested in receiving further comments on § 154.102 for future consideration. If we were to amend the definitions of "individual market" and "small group market" in § 154.102 to

include individual coverage and small employer coverage sold through associations in the rate review process, the amendment will only be applied prospectively.

We recognize that some States may be unable to review proposed rate increases for coverage sold through associations in circumstances in which such association coverage is viewed as large group coverage under State law and State law does not provide for review of rate increases in the large group market, or the State otherwise lacks legal authority to review such rates. In that case, CMS could review the proposed increases for those products. Whether or not a State does or may be unable to review rate increases for association coverage is not a criteria for determining whether it has an Effective Rate Review Program.

In addition, we are seeking comments to address the following questions:

1. Do States currently review rate increases for association and out-of-State trust coverage sold to individuals and small groups, regardless of whether the policies are situated in or outside of their States?

2. How many such rate filings do States receive for association and out-of-State trust coverage?

3. How prevalent are association and out-of-State trust coverage arrangements? What percentage of individual market and small group market business is sold through associations and out-of-State trusts?

4. In which States is association and out-of-State trust coverage commonly purchased by individuals and small groups? Where are out-of-State trusts typically situated?

5. Why do some individuals and small employers purchase coverage through associations and out-of-State trusts rather than the traditional markets? Are there particular groups of individuals or types of small employers that typically purchase coverage through associations and out-of-State trusts? What organizations (other than issuers) typically sponsor, endorse, or market association and out-of-State trust arrangements?

6. How do rate increases for association and out-of-State trust coverage sold to individuals and small groups compare to rate increases in the traditional market? What explains the differences (if any) between rate increases for association and out-of-State trust coverage and traditional market coverage?

Once we receive and review the comments, we will make a determination on whether to amend § 154.102 of the rule to include

individual and small employer health insurance coverage sold through associations in the rate review process. Meanwhile, nothing prohibits a State from reviewing rates of coverage sold through associations if it already does so or amends its laws in the future to do so.

b. Product. The proposed rule would define “product” as a package of health insurance coverage benefits with a discrete set of rating and pricing methodologies offered in a State.

Comment: Several industry commenters raised concerns that the definition of product was not consistent with State definitions and urged CMS to defer to such State definitions. Some commenters further contended that it would be administratively cumbersome to develop a new Federal product classification system that did not align with existing State classification systems.

Response: While we have not modified the proposed rule’s definition of product in this final rule, we believe that the definition is sufficiently flexible to accommodate existing State definitions, and that, as a practical matter, issuers will not have to reclassify their products to comply with the rate review process. Further, this definition is intended to track closely with the definition of health insurance product for purposes of the web portal, 45 CFR 159.110. We expect that in most cases issuers will be able to use their existing identification numbers for health insurance products under the Health Insurance Oversight System (HIOS) for reporting rate increases to CMS.

c. Rate Increase. The proposed rule would define “rate increase” as an increase in the rates of a specific product in the individual or small group market.

Comment: Several industry commenters supported CMS’ decision to base the threshold standards on rates, rather than premiums. They noted that the distinction between premiums and rates was explained in the proposed rule’s preamble and recommended that this discussion be incorporated into the final rule itself.

Response: We do not believe it is necessary to repeat the discussion in the proposed rule, as we are adopting the proposal described in that discussion, and that discussion applies to this final rule.

d. State. The proposed rule would define “State” using the definition provided in section 2791(d)(14) of the PHS Act.

Note: We note that the definition in 2791(d)(14) of the PHS Act includes the

States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and Northern Mariana Islands.

3. Applicability (§ 154.103)

The proposed rule generally would be applicable to all health insurance issuers offering coverage in the small group or individual markets in a State. The proposed rule would not apply to grandfathered health plan coverage, as defined in 45 CFR 147.140, and to insurance coverage that meets the “excepted benefits” definition set forth in section 2791(c) of the PHS Act.

Comment: State regulators, industry, and employers generally agreed that the large group market should not be subject to the final rule, noting that large employers are sophisticated purchasers, that rates generally are based on each large employer’s own experience, and that the proposed rule’s filing requirements were not aligned with State large group market practices. In contrast, some provider commenters and a labor organization recommended that the large group market be subject to the final rule, noting the rate increases that large groups have faced and the consolidation that has occurred in the health insurance industry. Lastly, one State regulator noted that rates for mid-sized employers (that is, those with 51 to 99 employees) are only partially experience-rated and that a rate review process could be warranted for them, as well.

Response: We understand that many employer groups at the smaller end of the large group spectrum are only partially experience-rated, but we have not included them in the scope of the final rule because few States review rates for large groups. However, we will monitor rate increases in that market segment using a variety of sources including data from the rate review grant program and assess whether future amendments to the final rule may be warranted.

Comment: One commenter suggested that grandfathered plans be included within the scope of the final rule.

Response: Section 1251 of the Affordable Care Act provides that section 2794 of the PHS Act does not apply to coverage that was in effect on March 23, 2011 and retains grandfather status. If coverage loses its grandfather status, then PHS Act section 2794 of the PHS Act will apply.

Comment: One provider commenter recommended that dental and vision plans be included within the scope of the final rule. The commenter stated that rates for these products have increased significantly due to lack of

regulation and noted the importance of such coverage to children.

Response: We have maintained the exclusion for excepted benefits (including limited scope dental and vision benefits) as defined under section 2791(c) of the PHS Act because we believe Federal and State resources are most effectively focused on increases that affect the affordability of basic medical coverage. We do not believe that rate increases for excepted benefit plans such as limited scope dental and vision benefits have the same impact on individuals and small employers as rate increases for basic medical coverage that includes benefits for hospital and physician services. States may review these rates if permitted under State law.

Comment: One commenter recommended that retiree-only plans be included within the scope of the final rule when current or former employees pay for substantial portions of the premium increases.

Response: While it is possible that some State filing laws may apply to such coverage, we have not required that health insurance coverage provided to retiree-only plans be subject to this rule. We note that many retiree-only plans are self-funded and thus would not constitute health insurance coverage subject to section 2794 of the PHS Act.

B. Subpart B—Disclosure and Review Provisions

1. Rate Increases Subject to Review (§ 154.200)

Under the proposed rule, CMS or the applicable State would review those rate increases that meet or exceed specified thresholds to determine if they are unreasonable. (We understand that many States review all rate increases in the applicable markets; nothing in this rule affects State laws or practices with respect to rate increases below the relevant threshold.) Rate increases would be subject to review if they are 10 percent or more and either: (1) are filed in a State on or after July 1, 2011; or (2) are in a State that does not require rate increases to be filed, and are effective on or after July 1, 2011. For rate increases filed in a State during calendar year 2012 and thereafter, or effective in calendar year 2012 and thereafter in a State that does not require rate increases to be filed, rate increases that meet or exceed State-specific thresholds determined by the Secretary for the applicable calendar year (or 10 percent if applicable State-specific thresholds are not determined by the Secretary) would be subject to review. The State-specific thresholds would be published in the **Federal**

Register no later than the September 15th prior to each calendar year to which they apply.

To determine whether the specified threshold is met or exceeded, the weighted average increase for all enrollees subject to the rate increase would be used. Rate increases during the 12 month period that precedes the date on which a rate increase is effective are aggregated to determine whether the specified threshold is met or exceeded.

Comment: Some State regulator and industry commenters believed that the proposed rule underestimated the number of rate increases that would be above the 10 percent threshold, with some commenters claiming that virtually all proposed rate increases would be captured under that threshold. Industry commenters contended that the 10 percent threshold did not represent a fair balance of capturing a reasonable number of proposed rate increases and did not track with recent rate increase trends. Some State regulator and industry commenters noted that section 2794 of the PHS Act called for the review of “unreasonable” increases, and that increases above 10 percent are not necessarily unreasonable. Other industry commenters asserted that the threshold was arbitrary and low. They claimed this threshold would stigmatize actuarially appropriate rates, bias State review, deluge consumers with confusing information, and place significant administrative burdens on issuers. Industry commenters recommended that the threshold be based on a broader range of factors including medical cost inflation, adverse selection, deductible leveraging, and required benefit changes, among others.

Consumer, provider, and some State regulator commenters, in contrast, argued that the 10 percent threshold was too high. Commenters listed numerous concerns including: (1) The threshold did not consider the cumulative impact of increases from multiple years and could encourage issuers to target just below the threshold; (2) many rate increases below 10 percent could be problematic from an actuarial perspective; and (3) a threshold designed to be above medical trend would not pressure issuers into taking steps to moderate growth in medical costs. In addition, some commenters recommended that all proposed increases be subject to review.

Response: We believe that 10 percent continues to be an appropriate initial threshold for determining which rates will be subject to review based on the analysis of the trend in health care costs and rate increases provided in the

preamble to the proposed rule. The 10 percent transitional threshold balances the need to provide more disclosure to consumers while avoiding undue administrative burdens on other stakeholders. This threshold should not cause consumers to be overwhelmed with information since they likely will only review rate information concerning their current plans or those which they are considering buying. With respect to the commenter focusing on the word “unreasonable” in section 2794, we believe that to identify and review unreasonable rates prior to implementation, it is necessary to review potentially unreasonable rates to assess their reasonableness. Lastly, we note that the 10 percent threshold is intended to be transitional, until State-specific thresholds are put in place.

Comment: Several commenters suggested that the proposed July 1, 2011 effective date for the rate review program did not provide States and health insurance issuers with adequate time to come into compliance with a final rule. Many State regulator commenters suggested that the proposed effective date be delayed until January 1, 2012 and noted that later effective dates would allow the rate review program to begin with State-specific thresholds rather than the 10 percent threshold. One State regulator commenter suggested that the effective date be 6 months after promulgation of the final rule. One industry commenter proposed that the effective date be July 1, 2012, expressing concern that there would not be enough time between issuance of the final rule and a July 1, 2011 effective date for issuers to develop and implement necessary system changes. Several industry commenters stated that they currently are in the process of developing rates for July 1, 2011 effective dates and recommended that the proposed rule not apply to those rates in States without current rate filing requirements.

Response: In response to these comments, we have moved the effective date in this final rule from July 1, 2011 to September 1, 2011 and maintained the initial, transitional 10 percent threshold. This effective date is intended to ensure that proposed 2012 rate increases meeting or exceeding the 10 percent threshold will be reviewed by either CMS or the applicable State. Further delay could mean that many rate increases for 2012 will not be subject to review. We do not deem further delay in starting the rate review program to be desirable given that stakeholders now have been able to provide us with valuable feedback concerning the program’s design and we

are prepared to initiate the program. We note that issuers will not be required to provide data beyond what the majority of States already require to be filed in support of proposed rate increases. We will be offering further guidance and training to assist issuers in complying with their obligations under the program.

Comment: State regulator and industry commenters generally expressed support for State-specific thresholds. Some consumer commenters expressed concern that use of State-specific thresholds would reward inefficient insurance markets with higher thresholds. They recommended either the use of a national threshold or the lower of a national or State-specific threshold. Alternatively, some consumer commenters recommended that CMS apply downward adjustments to State-specific thresholds in inefficient insurance markets. State regulator commenters recommended that States be able to establish their own review thresholds, or that, at a minimum, CMS consult with States in developing the State-specific thresholds. State regulator commenters also recommended that the final rule provide more detail on CMS's process for determining State-specific thresholds and include a process by which States could ask CMS to reconsider State-specific thresholds they considered inappropriate. Industry commenters generally were supportive of more State involvement in developing State-specific thresholds.

Many commenters provided recommendations on the methodology for establishing the State-specific thresholds applicable to 2012. Industry commenters raised concerns that a threshold tracking loosely with medical trend, but not other factors, would not sufficiently account for expected rate increases and emphasized that the threshold's underlying factors should have an appropriate actuarial basis. Additionally, some industry commenters said that the threshold should take into account possible impacts from the Affordable Care Act on proposed increases. As noted, many consumer and provider commenters stated that the 10 percent threshold was too high and recommended that CMS use lower thresholds in 2012. Some consumer commenters stated that the threshold should be based solely on medical trends, while others recommended that it be based on multiple factors, including adjustments for inefficient insurance markets and issuers' medical loss ratios.

Many commenters urged CMS to act quickly to develop the State-specific thresholds for 2012, noting that health

insurance issuers were already developing their proposed rates and that even if the State-specific thresholds were released by September 15, 2011, most of the 2012 increases would be missed. Several commenters noted the need to monitor State-specific thresholds closely on an ongoing basis to keep up with market trends and address potentially unintended consequences (for example, under- or over-inclusive thresholds).

Response: As noted earlier, the 10 percent threshold is intended to be transitional and we believe that this initial phase of the rate review program will enable CMS and the States to gather information that will be helpful in developing the State-specific thresholds. CMS will immediately begin work with the States and the NAIC to develop a process and identify data and methodologies for setting State-specific thresholds, so that the first State-specific thresholds can be effective for the twelve-month period beginning on September 1, 2012. We plan to update the State-specific thresholds annually, although the 10 percent threshold will apply in a State if a State-specific threshold has not been established for that State. We will publish a notice concerning the applicable thresholds no later than June 1 of each year beginning in 2012.

Comment: Commenters offered various interpretations concerning how rate increases should be calculated and how the weighting concept should work under the proposed rule, while others asked for clarification on these issues. Specifically, one commenter understood the proposed rule to mean that rate increases would be calculated as the overall average percentage increase between the old premium and the new premium, while another believed that rate increases would be calculated as the percentage change between the old revenue and the new projected revenue. With respect to weighting, some commenters interpreted the proposed rule to mean that the increase percentage be weighted by the number of policies, arguing that a subgroup with a lower premium should not be treated the same as another subgroup with a larger premium but an equal percentage increase.

Response: We have modified the final rule to clarify the issues raised by these comments. We believe that the rule's method for calculating a rate increase (that is, the average increase over all policies weighted by premium volume) is arithmetically identical to calculating the rate increase as the overall average percentage increase between the old premium and the new premium. In

addition, the rule's method for calculating a rate increase could be applied such that it is the same as calculating the rate increase as the percentage change between the old revenue and the new projected revenue. With respect to weighting, we note that weighting should not be done based on the number of policies; rather, premium volume is the appropriate weighting factor.

2. Unreasonable Rate Increase (§ 154.205)

The proposed rule would set three criteria that CMS would use in determining whether a rate increase is excessive, unjustified, or unfairly discriminatory, and, therefore, unreasonable. First, an increase would be considered excessive if it causes the premium to be unreasonably high in relation to benefits. In making this determination, CMS would consider whether: (1) The rate increase would result in a projected medical loss ratio below the applicable Federal standard; (2) one or more of the assumptions is not supported by substantial evidence; and (3) the choice of assumptions (or combination thereof) is unreasonable. Second, an increase would be considered unjustified if the issuer provides data or documentation that is incomplete, inadequate, or otherwise does not provide a basis to determine whether the increase is reasonable. Third, an increase would be considered unfairly discriminatory if it results in premium differences between insureds with similar risks that are not permitted under State law or, if there is no applicable State law, does not reasonably correspond to expected differences in costs.

Comment: Commenters representing State regulators, industry, and a professional association expressed concern that the definition of "unreasonable rate increase" in the proposed rule did not include a prong related to the adequacy of the proposed rates.

Response: We acknowledge that inadequate rate increases can be problematic. For example, inadequate rate increases can lead to larger increases for consumers in subsequent years or even have a negative impact on an issuer's overall financial condition. Section 2794 of the PHS Act is not primarily concerned with rate increases that are too low and does not identify adequacy among the criteria to be considered when determining unreasonableness. Therefore, we did not include adequacy as a prong of the unreasonableness test that we will use when reviewing rates under the final

rule. We note that many States do explicitly consider the adequacy of rates during their reviews, and nothing in this regulation prevents or prohibits a State from continuing to consider this factor in their review in the future.

3. Review of Rate Increases Subject to Review by CMS or by a State (§ 154.210)

The proposed rule sets forth the factors that would be used by CMS to determine whether CMS would review rate increases subject to review or whether CMS would adopt the determinations made by a State. To the extent that a State had an Effective Rate Review Program in a given market, as determined by CMS, and provided to CMS its final determinations whether an increase is unreasonable, CMS would adopt that State's determinations. A State's final determination would need to include an explanation of its analysis and be provided to CMS within five business days following its determination. In all other situations, CMS would review rate increases subject to review.

Comment: One commenter argued that since section 2794 of the PHS Act requires CMS to establish a rate review process "in conjunction with States," CMS lacked authority to review rates in those States that did not have Effective Rate Review Programs. In contrast, a commenter representing business groups expressed support for the proposed rule's approach to CMS establishing a rate review program in conjunction with the States.

Response: We interpret the requirement that the rate review program be established "in conjunction with States" as requiring that it defer to rate review in the States to the extent consistent with the goals of the Affordable Care Act. The rate review program established by this rule defers to State law and provides that, for States with Effective Rate Review Programs, CMS will adopt their determinations as to whether rate increases are unreasonable. We do not view this requirement as barring CMS from reviewing rates or collecting any information in those States that do not have Effective Rate Review Programs.

4. Submission of Disclosure to CMS for Rate Increases Subject to Review (§ 154.215)

The proposed rule would require health insurance issuers to submit a "Preliminary Justification" for all rate increases subject to review. Parts I (rate increase summary) and II (written description justifying the rate increase) would be provided to CMS and the applicable State (if the State receives

such submissions). In addition, Part III (rate filing documentation) would be provided to CMS when it is reviewing the rate increase. Health insurance issuers may submit a combined Preliminary Justification for rate increases affecting multiple products if their claims experience is aggregated and the rate increases are the same across all of the aggregated products.

Part I of the Preliminary Justification would be required to include: (1) Historical and projected claims experience; (2) trend projections related to utilization and service or unit cost; (3) any claims assumptions related to benefit changes; (4) allocation of the overall rate increase to claims and non-claims costs; (5) per enrollee per month allocation of current and projected premium; (6) current loss ratio and projected loss ratio; (7) three-year history of rate increases for the product associated with the rate increase; and (8) employee and executive compensation data from the health insurance issuer's annual financial statements.

Part II would include a simple, brief narrative describing the data and assumptions used to develop the rate increase, including the rating methodology, the most significant factors causing the increase, and a brief description of the policies' overall experience.

Part III, submitted in cases where CMS is reviewing a rate increase, would be required to include the following elements: (1) Description of the type of policy, benefits, renewability, general marketing method, and issue age limits; (2) scope and reason for the rate increase; (3) average annual premium per policy, before and after the rate increase; (4) past experience and any other alternative or additional data used; (5) a description of how the rate increase was determined, including the general description and source of each assumption used; (6) the cumulative loss ratio and a description of how it was calculated; (7) the projected future loss ratio and a description of how it was calculated; (8) the projected lifetime loss ratio that combines cumulative and future experience and a description of how it was calculated; (9) the Federal medical loss ratio standard in the applicable market to which the rate increase applies, accounting for any adjustments allowable under Federal law; and (10) if the projected future loss ratio is less than the applicable Federal medical loss ratio, a justification for this outcome. CMS would accept a copy of a rate filing submitted to a State that included each of these elements. CMS would request additional information from health insurance issuers if their

Part III submissions lacked sufficient information for CMS to determine whether rate increases were unreasonable. Issuers would have five business days to supply the additional information. The data which issuers are required to provide in the Preliminary Justification contains less detail and therefore will be less burdensome for issuers than what is called for in the NAIC Model for Individual Health Insurance Rate Filings. This data is readily available to issuers and is generally included in rate filings which they make today.

CMS would promptly make Parts I and II of the Preliminary Justifications available through the healthcare.gov Web site. In addition, in cases where CMS receives Part III, CMS would post on the CCIIO Web site any information not designated as "confidential," as defined under CMS's Freedom of Information Act regulations, 45 CFR 5.65. CMS would review information designated as "confidential" and would post it only if CMS determined that such information was, in fact, subject to disclosure under 45 CFR 5.65. Lastly, the healthcare.gov Web site would include a prominent disclaimer that stated: "The Preliminary Justification is the initial summary information regarding the rate increase subject to review and does not represent a determination that the rate increase subject to review is an unreasonable rate increase."

Comment: Consumer commenters recommended strengthening the proposed rule's disclosure requirements by requiring additional information in Part I, II, and III of the Preliminary Justifications concerning average rate increases, historical rate increases, medical price and utilization changes, provider reimbursement and contracts, administrative costs (including costs related to medical management, marketing, lobbying, travel and association dues), and transfers of funds to affiliated companies. Provider commenters recommended similar disclosures concerning rate increases and administrative costs. One consumer commenter also suggested that sample rates be provided for persons with the same ages and family composition so that consumers could see how rate increases compared between health insurance issuers. Some State regulator commenters recommended that certain elements of the Preliminary Justification be revised or omitted to conform more closely to current reporting requirements imposed on issuers. One State regulator commenter recommended that executive compensation information not be

included in the Preliminary Justification, or, alternatively, that CMS explain how this information would help States evaluate a proposed increase.

Many industry commenters argued that much of the information required in the Preliminary Justification would not be useful to consumers and could cause them unfairly to view the proposed rates as unreasonable. For example, they asserted that rate increase history and employee compensation generally were not taken into account during actuarial reviews. They also expressed concern that a large proportion of consumers would receive a confusing deluge of information concerning rates subject to review, given their estimates on the volume of proposed increases that would exceed the thresholds.

Response: We generally believe that Parts I and II of the Preliminary Justification will provide consumers with sufficient detail concerning the factors influencing proposed rate increases, without being unduly confusing to consumers. Accordingly, the final rule continues to provide that Part I and II will be publicly posted. We have modified or eliminated certain reporting elements in the final rule as recommended by State regulator commenters. In Part I, medical loss ratio data has been removed because it can be computed from remaining Part I elements and therefore was redundant. (We note that medical loss ratio data continues to be a distinct reporting requirement for Part III.) The requirement to report executive and employee compensation data was also removed because these amounts would represent only a very small proportion of an overall rate increase when allocated by product and member month, and, consequently, would not be helpful to consumers in showing the primary rate increase drivers. We also added the phrase “as determined by the Secretary” in § 154.215(e) to allow HHS discretion in the future to respond to changes in the market and input from stakeholders as to what elements in Part I are most helpful to consumers. Finally, we removed the explanation of the rating methodology from Part II in order to keep Part II brief, non-technical, and understandable to consumers.

Comment: Some industry commenters recommended that CMS allow issuers to aggregate and report multiple products at the same level of aggregation as permitted under State law, without requiring that the same rate increase be applied to all of the aggregated products. These commenters stated it would be administratively burdensome for CMS to adopt an aggregation

standard that differed from current State requirements. Many consumer and provider commenters expressed concern that allowing aggregated filings for products would mask rate increase variations between different products.

Response: Our understanding is that some States review rate filings at a product level, while other States review rate filings on an aggregated product basis, particularly in community-rated environments. The final rule maintains the proposed rule’s standard, which accommodates both State approaches. Where filings are made on an aggregated product basis, the same claim experience must have been used to develop the increases and the proposed increases must be the same for each of the different products to ensure that issuers cannot mask high increases for certain products within the combined filings. To the extent that this approach represents a change for some issuers, the burden should be minimal since the rule merely requires that they report existing information in a different fashion. We believe that this aggregation standard appropriately balances the need for increased transparency with current State rate filing requirements and actuarial practices.

Comment: Many consumer commenters urged that Part III of the Preliminary Justification not be given confidential treatment, reasoning that the public’s right to information concerning rate increases outweighed issuers’ proprietary interests in such information. One commenter noted that, for example, issuers potentially could designate actuarial memoranda and risk-based capital information as confidential, thereby leaving consumers without important information needed to scrutinize proposed rate increases. Another consumer commenter recommended that issuers be required to submit data on provider reimbursement and contracts and that issuers not be permitted to designate such data as confidential. While provider commenters generally recommended that as much information as possible from the Preliminary Justification be publicly released, they expressed concern about maintaining the confidentiality of provider reimbursement rates. Industry commenters were concerned about the impact of disclosing market sensitive information and generally recommended that the information in Part III be kept confidential and not disclosed. Industry commenters requested that CMS provide additional information on how the “confidential” information exemption under the Freedom of Information Act (FOIA), 5

U.S.C. section 552, would apply so that they could designate information in Part III of the Preliminary Justification appropriately. They also requested more guidance on CMS’s review and appeal process for FOIA requests and disclosures.

Response: The final rule essentially adopts the confidentiality approach taken in the proposed rule; that is, information contained in Part III of a Preliminary Justification will be posted on our Web site unless the FOIA exemption for trade secrets and confidential commercial or financial information applies. As a Federal agency, we generally are required to utilize the FOIA standard in determining confidentiality. As discussed in more detail in the preamble to the proposed rule, CMS’s FOIA rule, 45 CFR Part 5, establishes the process and standards that generally apply to determining whether information designated as confidential is subject to disclosure. Issuers will be able to designate the information that they believe is protected by the exemption and we will determine whether the exemption applies.

We reviewed the approaches currently taken by States concerning the public disclosure of rate filings. Some States make all parts of a rate filing public; some States provide standards for which parts of a rate filing will be made public; and other States follow a freedom of information process and standard under State law that is similar to FOIA. Based on a review of State filing guidelines and State Web sites, it appears at least 12 states do not redact any information when making rate filings available to the public. Given that Part III is based on State rate filing requirements, this means that many States do not regard the types of information found in Part III to be confidential or protected from disclosure. Based on the fact that the information contained in Part III appears to be widely available across the country and that many States already are making this information available, it may be difficult for an issuer to assert that the information in Part III is confidential or protected from disclosure under Federal law.

Comment: Industry commenters recommended that issuers be provided additional time beyond five business days to respond to an inquiry from CMS regarding an incomplete Part III of the Preliminary Justification. Commenters noted that, for example, a more complex request might require an issuer to gather and organize information from different internal departments, which could take longer than five business days.

Response: We have modified the final rule so that, after receiving a request from CMS, an issuer will have 10 business days to respond to provide additional Part III information.

Comment: Several State regulator, consumer, and industry commenters expressed concerns that the proposed rule's disclaimer language would be misleading to consumers and that a clearer description of both the purpose of the Preliminary Justification and the rate review process was needed. State regulator and industry commenters requested an explicit statement that rates subject to review had not yet been determined to be unreasonable by a State or CMS. Commenters also recommended including statements regarding: (1) The availability of additional information if a rate was determined to be unreasonable; (2) the actuarial factors that impact the reasonableness of rates; (3) the possibility that a proposed increase might change prior to implementation; and (4) whether a product was available for purchase notwithstanding review of its proposed rates.

Response: We have modified the final rule to state more generally that a disclaimer will accompany the Preliminary Justifications posted on our Web site. Guidance concerning this disclaimer will be provided at a later date and the commenters' concerns will be considered when that guidance is developed.

5. Timing of Preliminary Justification (§ 154.220)

The proposed rule provides that if a State requires a proposed rate increase to be filed with the State prior to implementation of the increase, the health insurance issuer must send CMS and the applicable State the Preliminary Justification on the date the issuer submits the proposed increase to the State. For all other States, the health insurance issuer must send CMS and the applicable State the Preliminary Justification prior to the implementation of the rate increase.

Comment: A few State regulator commenters suggested that Preliminary Justifications should not be posted unless a rate was found to be unreasonable. These commenters expressed concern that posting Preliminary Justifications prior to the proposed increases' evaluation would cause consumer confusion, lead to unsuitable replacements of coverage, and provide opportunities for misuse of information. In addition, commenters noted that some States did not allow disclosures concerning rate filing information until rates are approved. In

contrast, other State regulator commenters supported the requirement that the Preliminary Justification be posted immediately upon receipt. Several consumer commenters recommended that policyholders and the public be given adequate notice of proposed rate increases prior to increases going into effect. These commenters generally suggested that issuers file proposed rates with the States and give consumers notice of the proposed increases 60 or 90 days before they go into effect. One commenter suggested that patient advocacy groups be given specific notice concerning proposed increases that were higher than medical inflation.

Response: Section 2794 of the Act requires that issuers submit to the Secretary and the relevant State a justification for an unreasonable rate increase before the rate is implemented. We considered two alternatives to implement that provision. The first would be to establish a federal regulatory requirement that a rate cannot go into effect until it has been reviewed and determined to be reasonable or unreasonable. At that point, justifications could be submitted only for those rates that were determined to be unreasonable, prior to their being implemented. Such a federal requirement would be inconsistent with the "file and use" laws in many States, which provide that a rate may go into effect as soon as it is filed. We concluded that overriding State law in this respect was not the best approach.

Alternatively, the approach taken in the proposed rule, which requires a Preliminary Justification to be submitted at the time a rate increase subject to review is filed, assures that there will be a justification for increases for all rate increases that ultimately are determined to be unreasonable, without requiring any change in current State law or practice for reviewing rates. We believe that requiring the posting of the Preliminary Justification before a final determination is made both satisfies the requirements of the Affordable Care Act and assures that consumers will better understand why their issuers are proposing rate increases that meet or exceed the subject to review threshold.

In addition, the disclaimer language on our Web site will be modified to better inform consumers of the purpose of the Preliminary Justification and to make clear that its posting is not a determination that the proposed rate increase is unreasonable.

6. Determination by CMS or a State of an Unreasonable Rate Increase (§ 154.225)

When CMS reviews a rate increase subject to review, it will post on its Web site a final determination and a brief explanation of its analysis within five business days following the determination. If the rate increase is determined to be unreasonable, CMS will also provide this information to the health insurance issuer.

When a State reviews an increase subject to review, CMS will adopt the State's final determination and post it on the CMS Web site. If a State determines that the rate increase is unreasonable, but the health insurance issuer is legally permitted to implement the increase under State law, CMS will provide the State's final determination and explanation to the issuer within five business days of CMS receiving the information from the State.

Comment: One State commenter suggested that States with Effective Rate Review Programs not be required to post brief explanations and analyses that were more in-depth than those posted by CMS in cases where it reviews rates.

Response: We have modified the final rule to clarify that the brief explanations and analyses posted by CMS and States are intended to be consistent in format and content.

Comment: Numerous industry commenters suggested that CMS establish safe harbors or expedited rate review procedures. For example, some commenters suggested that if a health insurance issuer's proposed rate increases were expected to satisfy the Federal medical loss ratio standard, the increases should be exempt from review. Another commenter suggested that proposed rates in insurance markets that were determined to be competitive should either be exempt from review or subject to an expedited process. One commenter stated generally that the review process applied should vary based on the circumstances of the proposed increase.

Response: We have not modified the final rule to provide safe harbors or expedited rate review procedures given that many factors are relevant in determining whether a particular proposed rate increase is unreasonable, thus supporting the need for a more detailed review process.

7. Submission and Posting of Final Justifications for Unreasonable Rate Increases (§ 154.230)

If a health insurance issuer declines to implement a rate increase that has been determined to be unreasonable, or

chooses to implement a lower increase, under the proposed rule, the issuer would be required to provide CMS timely notice of its decision. A lower increase that meets or exceeds the applicable thresholds for review would require a new Preliminary Justification. However, if an issuer chooses to lower its request for a proposed increase while the increase is under review and before a determination or unreasonableness has been made, the issuer can do so by filing a modification to the filing under review. If the revised rate falls below the review threshold, the review will cease and the revised rate will be displayed on the posting.

If a health insurance issuer implements an unreasonable rate increase, it must, within 10 days of the later of implementing the increase or receiving the final determination, provide CMS with a "Final Justification" responding to CMS's or the State's determination, using information consistent with that provided by the issuer in the Preliminary Justification. The health insurance issuer must prominently post on its Web site: (1) the portions of the Preliminary Justification posted on the CMS Web site; (2) CMS's or the State's final determination; and (3) the issuer's Final Justification. This information must be made available on the issuer's Web site for at least three years. In addition, CMS will make an issuer's Final Justification available through the healthcare.gov Web site for three years.

Note: We did not receive any major comments on this section.

C. Subpart C—Effective Rate Review Programs

CMS's Determination of Effective Rate Review Programs (§ 154.301)

Under the proposed rule, CMS would apply the following criteria in evaluating whether a State has an Effective Rate Review Program for the individual market and small group market, including different types of products within those markets. CMS will examine information publicly available concerning each States' authority to receive the data needed in order to review a proposed rate increase. This includes State statutes, regulations, bulletins, filing guidance, and so forth. CMS will also review available information that describes each State's practices in conducting rate reviews. This information primarily consists of State applications for rate review grants, quarterly reports of activity undertaken with grant funds, and conversations between CMS staff and state regulators relating to grant activities.

CMS will then conduct a phone call with each State insurance regulator to confirm the information CMS has gathered and to ask for any additional information the State believes is relevant to the determination of whether it has an Effective Rate Review Program.

CMS will notify States of its determinations by July 1, 2011, two months in advance of the date filings are first due pursuant to this regulation. States will have the right to bring any new information bearing on this decision to CMS at any time, and CMS will consider whether based on this new information the State should be determined to have an Effective Rate Review Program. CMS will also monitor States that have determined to be effective in order to ascertain that their processes continue to satisfy the requirements of the regulation.

CMS would consider whether the State receives data and documentation from issuers concerning rate increases sufficient to conduct an examination of the reasonableness of the assumptions used to develop proposed rate increases, the validity of the historical data underlying the assumptions, and the issuers' data related to past projections and actual experience. CMS also would consider whether the State conducts effective and timely reviews of the information submitted by issuers in support of proposed rate increases. The examination would need to include an analysis of: (1) Medical trend changes by major service categories; (2) utilization changes by major service categories; (3) cost-sharing changes by major service categories; (4) benefit changes; (5) changes in enrollee risk profile; (6) impact of over- or underestimate of medical trend in previous years on the current rate; (7) reserve needs; (8) administrative costs related to programs that improve health care quality; (9) other administrative costs; (10) applicable taxes and licensing or regulatory fees; (11) medical loss ratio; and (12) the health insurance issuer's risk-based capital status relative to national standards. Finally, the State's determination whether a rate increase is unreasonable would need to be made under a standard set forth in State statute or regulation.

CMS would determine whether a State has an Effective Rate Review Program for each market based on documentation and information received by CMS from the State or any other information otherwise available to CMS indicating that its rate review program meets these criteria. CMS would reserve the right to determine that a State no longer had an Effective Rate Review Program if it no longer met

these criteria. The NAIC individual rate filing guidelines—the basis of many states current rate review practices—require the collection and review of a larger, more detailed set of data than the review criteria provided in the rule. Thus, the review criteria provided in the rule incorporates practices that are already in place in many states.

Comment: The NAIC recommended that the final rule allow flexibility for States to conduct rate reviews within their statutory frameworks. One State regulator commenter recommended that the final rule defer to State law on what constitutes an Effective Rate Review Program and not require States to conform to any Federal definition of an Effective Rate Review Program. In the alternative, the commenter suggested that the NAIC establish rate review standards that could be required for State accreditation. In addition, some commenters including State regulators and an organization representing the actuarial profession generally recommended that reviews conducted by CMS and the States should be subject to the same standards under the final rule. For example, the commenter believed that the lists of informational elements required under § 154.215(g)(1) and § 154.301(a)(3) should be the same. Industry commenters argued that review standards in the proposed rule did not reflect the variation that currently exists among the States and the rule could drive States towards a national standard. Industry commenters also expressed concern that the criteria were overly prescriptive and that their application could be unduly subjective. Consumer and provider commenters expressed concern that the proposed rule's standards overall were too low and that States with limited review capabilities could be designated as having effective programs. Commenters also noted that the effectiveness of State review processes in practice, in addition to a State's statutory authority, was relevant to determining if an Effective Rate Review Program existed in a State.

Response: We believe it is necessary for the rule to set forth minimum review standards so that CMS can determine which States meet those standards and subsequently defer to their determinations concerning whether proposed rate increases are unreasonable. We agree with commenters that the minimum standards for reviews for CMS and the States should be consistent. Therefore, we have modified the proposed rule in this final rule so that the information that CMS will review in Part III of the Preliminary Justification will be the same information that will be reviewed

as part of a State Effective Rate Review Program under § 154.301(a)(3) and (4). In addition, we have modified § 154.301(a)(4) to clarify that CMS and States with Effective Rate Review Programs will have to take into consideration the various factors listed in paragraph (4) to the extent applicable to the filing under review. This change is meant to reflect that reviewers for CMS or the State will have flexibility to use their expert judgment in evaluating the relevance of the different factors in the context of a particular rate filing.

Comment: Many consumer commenters urged that public hearings and comment periods be required as part of an Effective Rate Review Program. One commenter recommended that excessive or frequent increases give rise to public hearings. Another commenter suggested that the public hearings be held at the health insurance issuer's expense if the proposed increase exceeded medical inflation. Lastly, one commenter suggested that issuers be required to mail information to consumers concerning proposed rate increases and their opportunities to participate in the rate review process.

Response: We did not include public hearings as a required element for Effective Rate Review Programs in deference to the fact that most States today do not hold public hearings as part of the rate review process. However, in response to the comments urging a greater opportunity for input from the public, we modified the final rule to require that in order to be deemed to have an Effective Rate Review Program, a State must: (1) Provide access on a State Web site to Parts I and II of the Preliminary Justifications for those proposed rate increases that meet or exceed the threshold, and (2) have a mechanism for receiving public comments on those proposed rate increases. For example, a State could provide Web site access either by directly posting the relevant Parts I and II on its own Web site or by posting a regularly-updated list of the relevant Parts I and II with a link to the CMS Web site where they can be found. States could choose to accept public comments through the mail, their Web sites, public hearings, or other means. We believe that posting the Parts I and II of the Preliminary Justifications and allowing public input will encourage public participation in the rate review process, but be less burdensome than requiring all States with Effective Rate Review Programs to hold public hearings. In addition, we added a parallel requirement in § 154.215 that we accept public comments on the proposed rate increases we review. We

note that CMS has encouraged States to undertake efforts to increase the transparency of their rate review programs under the grants authorized by PHS Act section 2794 and that many States are responding with innovative programs to increase public input. We also note that this is a criteria for States with Effective Rate Review Programs and not a requirement for a health insurance issuer filing for a rate increase.

Comment: Several consumer commenters stated that States should be required to have prior approval authority over proposed rate increases in order to qualify as having Effective Rate Review Programs.

Response: Prior approval authority over proposed rate increases can be an important part of a State's rate review program. States that have or propose this authority qualify for a supplemental performance grant under the grants provided under section 2794(b) of the PHS Act. Section 2794 of the PHS Act requires CMS to establish a process for reviewing unreasonable rates; it does not provide CMS with prior approval authority. We therefore did not think it would be appropriate for CMS to mandate that States have prior approval authority in order to qualify as having Effective Rate Review Programs.

Comment: Several State regulator and industry commenters asked for clarification concerning the role of medical loss ratios in the rate review process.

Response: Both Federal and State medical loss ratios are relevant to the rate review process. We recognize that aggregation standards and relevant time periods differ between this rule and the Federal medical loss ratio interim final rule, 45 CFR part 158. For purposes of this rule, when CMS is reviewing rates, we will consider whether a product, along with the other products in the same market with which it will be aggregated for purposes of the Federal medical loss ratio, will be reasonably likely to satisfy the Federal medical loss ratio standards on a projected basis. We note that an issuer's explanation with regard to its projected medical loss ratio in a Part III submission has no bearing on its obligations under section 2718 of the PHS Act (for example, medical loss ratio rebates). In addition, CMS will consider whether a product satisfies the applicable State medical loss ratio standards in those States in which it reviews rates. In the absence of a State standard for the individual market, CMS will apply NAIC Model 134-1, "Guidelines for Filing of Rates for Individual Health Insurance Forms." In the absence of a State standard for the

small group market, CMS will apply NAIC Model 134-1 until it releases its own guidelines for the small group market. The CMS guidelines will be released in future guidance and will be developed following a review of current State requirements and practices, medical loss ratio data, and other relevant information concerning the small group market.

Comment: Some State regulator and industry commenters recommended that CMS not mandate that risk-based capital information be reviewed as part of the rate review process, stating that use of such information is not part of most State rate review processes. Consumer commenters emphasized that the overall financial condition of an issuer is relevant and should be taken into account.

Response: We understand that few States specifically consider risk-based capital information as part of the rate review process, although many States do consider more general information concerning issuers' capital and surplus. Therefore, we deleted risk-based capital as a factor in the final rule and have replaced it with capital and surplus. We believe that information concerning an issuer's capital and surplus may be useful in certain instances (for example, where an issuer has low surplus levels and needs to build reserves, or conversely where an issuer might be able to moderate a rate increase without causing solvency concerns). In addition, we note that capital and surplus information is only one of several items that would be taken into account as part of the rate review process, many of which will be of greater importance than capital and surplus information in making a determination of whether a proposed rate is unreasonable.

Comment: Several commenters suggested different ways to use the Rate Review Grant Program to support State efforts to conduct effective rate reviews. Some consumer groups urged that the grant program be used to award funds, either directly or through States, to voluntary health agencies and other groups to educate the public about the rate review process and to assist them in selecting coverage appropriate to their individual circumstances. One consumer group commenter suggested that grant funds be used to develop rate review models that include financial incentives for issuers that meet predetermined goals and that implement cost containment, quality improvement, and clinical effectiveness measures. Another consumer group commenter recommended that the grant program should be used to encourage states to enact legislation necessary to

secure rate review and prior approval authority.

Response: Grants awarded during Cycle I of the Rate Review Grant Program are being used to improve State rate review programs in a number of ways. Grant funds are being used to hire actuaries, improve information technology systems, and expand State rate review authority. Transparency is another goal of the rate review grant program and many States submitted work plans to improve public engagement in the rate review process. Cycle II grants, to be awarded in the Fall of 2011, will be awarded to States that have developed, or are in the process of developing, Effective Rate Review Programs. In Cycle II, CMS also will offer supplemental awards to States that have or obtain prior approval authority during the three-year grant period. Improving quality, implementing cost containment, and clinical effectiveness measures, while laudable goals, are outside the scope of the rate review rule.

III. Provisions of the Final Rule

For the most part, this final rule incorporates the provisions of the proposed rule. Those provisions of this final rule that differ from the proposed rule are as follows:

- *Applicability (§ 154.103).* We deleted extraneous language.
- *Rate increases subject to review (§ 154.200).* We streamlined language concerning when the 10 percent or State-specific threshold will be applicable, provided additional information on State-specific thresholds, and clarified the rate increase calculation formula. In addition, we changed the program's effective date from July 1, 2011 to September 1, 2011. We also changed the date of the publication of state specific threshold to no later than June 1 of each year for the 12 month period that begins on September 1.
- *Review of rate increases subject to review by CMS or by a State (§ 154.210).* We clarified that CMS and the States will provide similar explanations on final determinations concerning unreasonable rates.
- *Submission of disclosure to CMS for rate increases subject to review (§ 154.215).* We replaced or deleted certain elements required for Parts I and II of the Preliminary Justification. In addition, we conformed the information requirements for Part III of the Preliminary Justification submitted to CMS to be the same as the information requirements for an Effective Rate Review Program maintained by a State; clarified that further instructions for Part III will be provided in guidance;

and provided issuers with 10 business days (instead of 5 business days) to respond to a request for more information from CMS concerning a Part III submission. We shortened the language describing how CMS will treat confidential information in Part III under FOIA. We stated that the disclaimer that will accompany the Preliminary Justifications will be provided in guidance. Lastly, we added a requirement that CMS accept public comments on the proposed rate increases it reviews.

- *Timing of Providing the Preliminary Justification (§ 154.220).* We clarified the section's title and changed the program's effective date from July 1, 2011 to September 1, 2011.

- *Determination by CMS or a State of an unreasonable rate increase (§ 154.225).* We clarified that CMS will make timely determinations whether proposed rate increases are unreasonable and that CMS and the States will provide similar explanations on final determinations concerning unreasonable rates. In addition, we made a technical correction to clarify that CMS will provide a State's final determination to an issuer within five business days (rather than five days) of receipt.

- *Submission and posting of Final Justifications for unreasonable rate increases (§ 154.230).* We made a technical correction to clarify that issuers have 10 business days (rather than 10 days) to submit a Final Justification.

- *CMS's determinations of Effective Rate Review Programs (§ 154.301).* We clarified that States will need to take into account the listed factors in conducting their rate reviews. We replaced the risk-based capital factor with a capital and surplus factor. We required that States provide access to Parts I and II of the Preliminary Justifications through their Web sites and accept public comments on them. Lastly, we clarified that CMS will determine whether a State had an Effective Rate Review Program based on the information available to CMS and that CMS will revisit these determinations in light of changed circumstances.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate

whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We requested comments on these requirements in the proposed rule. In addition, on March 1, 2011, CMS published a draft version of the Preliminary Justification in the **Federal Register** and requested public comments as required under the Paperwork Reduction Act (PRA). The public comment period closed on May 2, 2011, and 9 comments were submitted from consumer advocacy organizations, health insurance issuers, a state regulatory organization, and an actuarial professional association.

CMS has reviewed all of the comments and will release as soon as possible but no later than 7–10 days after publication of this final rule an updated version of the preliminary justification that incorporates the feedback received through the PRA comment process. The description of the preliminary justification in the final rule outlines the overall structure of the updated preliminary justification that is still pending release.

A description of the information collection requests is given in the following paragraphs with an estimate of the annual burden, and summarized in table A. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information. Because we have not yet made a determination on the comments received pertaining to the draft forms published on March 1, 2011, these estimates are not final and are subject to change. Further, the information collection requirements associated with this final rule will not become effective until approved by OMB. HHS will issue a notice in the Federal Register announcing OMB approval once it is obtained.

A. Background

Section 2794 requires the Secretary to develop, in conjunction with the States, a process for the annual review of unreasonable rate increases. The

regulation establishes a rate review program to ensure that all rate increases that meet or exceed an established threshold are reviewed by a State or CMS to determine whether the rate increases are unreasonable. Under the regulation, if CMS determines that a State has an Effective Rate Review Program in a given market, using the criteria set forth in the rule, CMS will adopt that State's determinations regarding whether rate increases in that market are unreasonable, provided that the State reports its final determinations to CMS, and explains the bases of its determinations. For all other States or markets, CMS will conduct its own review of rates that meet or exceed the applicable threshold to determine whether they are unreasonable.

Section 2794 directs the Secretary to ensure the public disclosure of information on unreasonable rate increases and justification for those increases. The regulation therefore develops a process to ensure the public disclosure of information on unreasonable rate increases and justifications for those increases. Section 2794 also requires that health insurance issuers submit a justification for an unreasonable rate increase to CMS and the relevant State prior to its implementation. The regulation therefore establishes various reporting requirements for health insurance issuers, including a Preliminary Justification for a proposed rate increase, a Final Justification for any rate increase determined by a State or CMS to be unreasonable, and a notification requirement for unreasonable rate increases which the issuer will not implement.

B. Information Collection Requirements (ICRs) Regarding the Rate Review Preliminary Justification Form (§§ 154.215 and 154.220)

This final rule describes the Preliminary Justification that each health insurance issuer would be required to submit to both CMS and States, if it is seeking to implement a rate increase that meets or exceeds the threshold described in § 154.200. The Preliminary Justification includes data supporting the potential rate increase as well as a written explanation of the rate increase. For those rates CMS will be reviewing, issuers' submissions must also include supplemental data and information that CMS will need to make a valid actuarial determination regarding whether a rate increase is unreasonable.

Each health insurance issuer seeking to implement a rate increase that meets or exceeds the established threshold

would be required to complete a Preliminary Justification. The Preliminary Justification consists of three Parts. Part I consists of a document (Excel spreadsheet) to be completed by issuers for all proposed rate increases that meet or exceed the threshold. Part II of the Preliminary Justification is a brief written narrative explaining the methodology used to derive the rate increase. Issuers would be required to submit to both CMS and the applicable State Parts I and II prior to implementation of a rate increase, regardless of whether CMS is reviewing the rate increase or adopting the State's review. Issuers typically calculate these figures in order to develop their rates and submit a rate filing to State regulators. The data elements and methodologies are commonly calculated by issuers and are often required by States that review rates.

Issuers will be required to complete Part III of the Preliminary Justification only when CMS rather than the State is reviewing a rate increase to determine whether it is unreasonable or not, and submit Part III to CMS only (and not to the applicable State). Part III of the Preliminary Justification defines an additional set of information that issuers must submit only when CMS is reviewing a rate increase. The information provided under Part III will allow CMS to make a valid actuarial determination as to whether the rate increase is unreasonable or not. If an issuer completes and submits Part III of the Preliminary Justification, but does not provide sufficient information for CMS to conduct its review, CMS will request the additional information necessary to make its determination. Issuers have 10 business days to respond to any request for outstanding information from CMS.

Using 2010 data, CMS estimates the number of rate filings in 2010 that would have been subject to the rule had it been in force to be between 4,580 and 5,059 in the individual and small group markets nationwide. CMS estimates that the total number of rate filings is expected to increase slightly in 2011, due in part to an increased number of issuers required to file based on those factors discussed in the impact analysis section.

Therefore, CMS estimates that, in 2011, there would be 6,733 rate filings subject to the rule. As discussed in the impact analysis section, CMS estimates that approximately 974 of these rate filings will require review under the rule because they meet or exceed the established threshold. CMS estimates the total number of burden hours to be 10,714.

C. ICRs Regarding State Determinations (§ 154.210 and § 154.225)

Under the final rule, if CMS determines that a State has satisfied specific criteria for an Effective Rate Review Program under § 154.301, CMS would adopt the State's determinations regarding whether a rate increase that meets or exceeds the established threshold is unreasonable, providing the State reports its final determinations to CMS and explains the basis of its determination as required under § 154.210(b)(2). As discussed in the impact analysis section, since many States are already performing these functions, the cost burden to States would be small and would largely be offset by rate review grants provided by CMS to help States improve their rate review processes. In those cases where a State does not have an Effective Rate Review Program, CMS will make its own determinations regarding whether a rate increase that meets or exceeds the established threshold is unreasonable.

CMS and the States would post on their Web sites the information contained in each Preliminary Justification for each rate increase subject to review under § 154.200. For consumer clarity, CMS will also post on its Web site the final disposition of each rate increase reviewed by either CMS or a State. Therefore, either a State or CMS would make a final disposition for all rate increases reviewed under the rule, similar to current rate filing practices under the NAIC System for Electronic Rate and Form Filing ("SERFF") or similar State-based filing systems.

As explained in the impact analysis section, CMS estimates that 974 rates would be reviewed under the rule because they meet or exceed the established threshold and that 25 to 35 States, in whole or in part based on market segment, would be reporting to CMS and posting dispositions on approximately two-thirds of these rates (or 649 filings) for at least one market. The RIA also estimates that reporting information from the State to CMS will require approximately 20 minutes per filing. Thus the annual burden for this requirement is approximately 214 hours. CMS believes that posting the final disposition would not pose any additional burden on States.

D. ICRs Regarding the Final Justification and Final Notification (§ 154.230)

The final rule requires health insurance issuers to submit to CMS and the relevant State a Final Justification for any unreasonable rate increase that would be implemented and to display this information on their Web sites. If an

issuer is legally permitted to implement an unreasonable rate increase and declines to implement the increase, the issuer will provide notice to CMS that it will not implement the increase. As discussed in the impact analysis section, CMS estimates that 417 issuers will submit an estimated 468 to 1,723 rates for review and that it will take between 6 to 16 hours to complete the entire justification process. CMS estimates that 974 rates will meet or exceed the threshold and for the purposes of providing an upper bound

of the potential number of final notifications further assumes issuers will implement 100 percent of rates found unreasonable.

E. ICRs Regarding CMS' Determinations of Effective Rate Review Programs (§ 154.301)

As discussed earlier in the preamble, CMS will determine whether a State's rate review program meets the requirements of an Effective Rate Review Program set forth in § 154.301(a) based on information received from the

State through the grant process, through review of applicable State law, and through any other information otherwise available to CMS. The information collection for the "Grants to States for Health Insurance Premium Review" is approved under OMB Control number 0938-1121. Since CMS does not believe additional data from States are necessary to make these determinations, we assume the additional burden from this provision is zero.

TABLE A—ESTIMATED ANNUAL BURDEN

Regulation section(s)	OMB control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total labor cost of reporting (\$)	Total capital/maintenance costs (\$)	Total cost (\$)
§ 154.210 ICRs Regarding State Determinations.	0938-New ..	35	649	.33	214	200	42,800	0	42,800
§§ 154.215, and 154.220, ICRs Regarding the Rate Review Preliminary Justification Form.	0938-New ..	417	974	11	10,714	200	2,142,800	0	2,142,800
§ 154.230, ICRs Regarding the Final Justification.	0938-New ..	417	974	.5	487	200	97,400	0	97,400
§ 154.230, ICRs Regarding the Final Notification.	0938-New ..	417	974	.5	487	200	97,400	0	97,400
Total	452	3,571	11,902	2,380,400	2,380,400

We initiated an information collection request under a separate notice and comment period from that associated with the proposed rule that was published on December 23, 2010 (75 FR 81004). Specifically, the 60-day **Federal Register** notice soliciting public comment on the aforementioned information collection requirements was published on March 1, 2011 (76 FR 11248) and the comment period closed on May 2, 2011. We plan to publish the requisite 30-day **Federal Register** notice to announce the formal submission of the information collection request to OMB and to announce another opportunity for the public to submit comments in the near future.

V. Response to Comments

Because of the large number of public comments we receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. A discussion of the comments we received is included in the preamble of this document.

VI. Regulatory Impact Analysis

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

A. Summary

As stated earlier in the preamble, this final rule implements section 2794 of

the PHS Act (as added by Section 1003 of the Affordable Care Act), which requires the Secretary, in conjunction with the States, to establish a process for the annual review of unreasonable increases in health insurance premiums (referred to in the rule as "rates"). This final rule outlines the methodology by which CMS would review proposed rate increases. This regulation implements statutory provisions designed to help make private health insurance more affordable, and to increase the transparency of the process by which health insurance issuers calculate premiums. CMS has quantified costs where possible and provided a qualitative discussion of the benefits and of the transfers and costs that may stem from this regulation.

In the preamble to this regulation, we solicit comments on whether we should amend the final rule to include individual and small employer coverage sold through associations in the rate review process. This final regulation does not specifically include such coverage in the rate review process unless the State reviews it as either individual coverage or small employer coverage. Many States currently consider coverage sold through associations as large group coverage, in which case it would not be subject to the rate review process of this regulation. Since we did not specifically

require in this regulation that coverage sold through associations be included in the rate review process, we did not include in this RIA an estimate of the additional burden of including association coverage in the rate review process. We do, however, include below a separate estimate of the burden associated with including association coverage in the rate review process for the purpose of soliciting comments on the burden estimate.

In the proposed rule we requested comments on the burden and cost estimates in the RIA but did not receive any such comments.

B. Executive Order 13563 and 12866

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a "significant regulatory action" although not economically significant, under section 3(f) of Executive Order 12866.

Accordingly, the rule has been reviewed by the Office of Management and Budget.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any one year); and a “significant” regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below, CMS has concluded that this final rule would likely not have economic impacts of \$100 million or more in any one year, nor would it adversely or materially affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities. This assessment is based primarily on the administrative costs to issuers of completing the Preliminary Justification form they are required to submit when proposing rate increases of 10 percent or greater, and on the costs to States and the Federal government of reviewing these justifications. As discussed below, CMS is not able to quantify the effect of this final rule on rates charged by issuers, and it is possible that the effect on rates will be large enough to cause the final rule to be considered a major rule. CMS solicited comments on this issue in the proposed rule but did not receive any response.

Nevertheless, CMS opted to provide an assessment of the potential costs, benefits, and transfers associated with this final rule.

1. Need for Regulatory Action

Consistent with the provisions in section 2794 of the PHS Act, this final rule requires health insurance issuers offering non-grandfathered coverage in the individual and small group markets to report information concerning rate increases to CMS and the applicable State if the proposed increase is 10 percent or higher. Section 2794(a) of the PHS Act requires the Secretary to “establish a process for the annual review of unreasonable increases in premiums for health insurance coverage.” The section further provides that issuers “submit to the Secretary and the relevant State a justification for an unreasonable premium increase prior to the implementation of the increase.”

Many States currently review rate filings in all or some portion of the insurance market, therefore, the burden of implementing this final rule on States will be small. In the States that do not currently conduct effective rate review, CMS will initially review those rate filings that meet or exceed the 10 percent threshold. CMS anticipates that those States will use the rate review grants described in the preamble to enhance their capacity for review. Moreover, CMS anticipates gradually transitioning rate review responsibilities to these States as they build their capacity and as a result, reducing Federal costs over time.

In addition, this final rule requires issuers proposing rate increases 10 percent and above to provide a Preliminary Justification for the proposed increase. That Preliminary

Justification will use data typically assembled by the issuers in computing their rate request. Because the Preliminary Justification requires the restating of existing data rather than the generation of new information, CMS expects the burden on issuers in filing the justification will be relatively small.

2. Summary of Impacts

In accordance with OMB Circular A-4, Table 1 below depicts an accounting statement summarizing CMS’ assessment of the benefits, costs, and transfers associated with this regulatory action. CMS limited the period covered by the regulatory impact analysis (RIA) to 2011 through 2013. Estimates are not provided for subsequent years because there will be significant changes in the marketplace in 2014 related to the offering of new individual and small group plans through the health insurance Exchanges, and the wide ranging scope of these changes makes it difficult to project results for 2014 and beyond.

As described in this RIA, CMS estimates that this regulatory action will result in better information for consumers about their health insurance premiums and is likely to lower premiums. The final rule also imposes costs on insurers associated with preparing and filing proposed rate increases, and imposes costs on State and Federal governments associated with reviewing proposed rate increases. In accordance with Executive Order 12866, CMS believes that the benefits of this regulatory action justify the costs.

TABLE 1—ACCOUNTING TABLE

Benefits:

Qualitative:

* Increased transparency in health insurance markets, promoting competition

* To the extent that unreasonable rate increases are prevented as a result of this rule, reduction in the deadweight loss to the economy from the exercise of monopolistic power by issuers

Costs:	Low estimate	Mid-range estimate	High estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized (\$millions/year)	11	15	20	2010	2011–2013
	10	14	19	2010	2011–2013

One-time costs to create systems to report data, and annual costs related to reporting data to the Secretary, providing rate increase justifications, and costs to the States and Federal government of reviewing the justifications

Transfers:

Qualitative:

* To the extent that rate increases are reduced as a result of this rule, money will be transferred from issuers/shareholders to consumers.

3. Qualitative Discussion of Anticipated Benefits, Costs and Transfers

a. Benefits

Reliable information on prices is a prerequisite for well-functioning competitive markets. Consumers in the individual and small-group health insurance markets, which are highly concentrated, may have difficulty knowing whether an increase in their premium is actuarially justifiable—for example, because it is due to a change in the scope of covered services—or whether it is the result of insurers exercising market power to set rates above the level that is actuarially justifiable.

The final rule subjects proposed rate increases of 10 percent or more to additional scrutiny in order to safeguard against this exercise of market power by insurers. The final rule’s reporting requirements should result in better information for consumers about prices, promoting competition and potentially increasing the volume of trade, thereby yielding a net benefit to society.

b. Costs

CMS has identified the primary sources of costs that will be associated with this final rule as the costs to issuers associated with reporting, recordkeeping, notifications, and the costs to State and Federal governments of conducting reviews of the justifications filed by issuers.

CMS estimates that issuers will incur approximately \$10 million to \$15 million in one-time administrative costs, and \$0.6 million to \$5.5 million in annual ongoing administrative costs related to complying with the requirements of this final rule from 2011

through 2013. In addition, States will incur very small additional costs for reporting the results of their reviews to the Federal government, and the Federal government will incur approximately \$0.7 million to \$5.9 million in annual costs to conduct reviews of justifications filed by issuers in States that do not perform effective reviews. Additional details relating to these costs are discussed later in this regulatory impact analysis.

C. Estimated Number of Affected Entities and Number of Rate Filings Meeting or Exceeding the Threshold and Subject to Review

Section 2794 of the PHS Act specifies that the rate review provisions apply to health insurance issuers offering individual or group health insurance coverage, not including grandfathered health plans. As discussed earlier in the preamble, in this context, the term “issuer” has the same meaning provided in 45 CFR 144.103, which states that an issuer is “an insurance company, insurance service, or insurance organization (including an HMO) that is required to be licensed to engage in the business of insurance in a State and that is subject to State law that regulates insurance (within the meaning of section 514(b)(2) of ERISA).” As discussed in the preamble, the rate review provisions in this final rule apply to issuers that offer individual and small group coverage, and these issuers will be required to submit a Preliminary Justification for rate increases meeting or exceeding the rate review threshold of 10 percent, to file with the Secretary and the applicable State a Final Justification for those rate increases found unreasonable, and

disclose information about the proposed increase, if implemented, on their Web sites. The following sections summarize CMS’ estimates of the number of entities and rate filings that would be affected by the requirements being implemented in this final rule.

D. Estimated Number of Affected Entities

The rate review provisions will apply to all health insurance issuers offering coverage in the individual and small group markets except for grandfathered plans. The number of issuers is 311 in the individual market and 342 in the small group market, for a total of 417 (unduplicated) issuers, as determined for the interim final rule for implementing the medical loss ratio requirements under the Affordable Care Act (**Federal Register**, December 1, 2010).

Table 2 shows the estimated distribution of the 417 issuers offering coverage in the individual and small group markets for the analytic sample used in this RIA.¹ Approximately 75 percent (311) of these issuers offer coverage in the individual market and 82 percent (342) offer coverage in the small group market. Additionally, CMS estimates that there are 34.8 million enrollees in coverage that will be subject to the requirements being proposed in this final rule, including approximately 10.6 million enrollees in individual market coverage and 24.2 million enrollees in small group coverage (estimated based on “life years” for 2009 NAIC Health and Life Blank filers, which excludes data for companies that are not required to file annual statements with NAIC).²

TABLE 2—ESTIMATED NUMBER OF ISSUERS SUBJECT TO THE RATE REVIEW REQUIREMENTS BY MARKET

Description	Issuers (companies) offering coverage ^{1 3}	% of total	Enrollees ²	% of total
	Number		Number (in thousands)	
			Total (Unduplicated)	
Number Offering Coverage In:				
Individual Market	311	74.6	10,603	30.5
Small Group Market ⁴	342	82.0	24,189	69.5

¹ Issuers represents companies (for example, NAIC company codes).

² Enrollment represents “life years” (total member months divided by 12).

³ Total issuers represents 2009 NAIC Health and Life Blank filers with valid data, which excludes approximately 8 percent of comprehensive major medical premium among NAIC filers. Also excludes data for companies that are regulated by the California Department of Managed Health Care.

⁴ Small group is defined based on the current definition (for example, 2 to 50 employees).

¹ The analytic sample excludes companies that are regulated by the Department of Managed Health Care in California, as well as small, single-State insurers that are not required by State regulators to submit NAIC annual financial statements. The excluded companies are estimated to account for approximately 9 percent of the comprehensive

major medical fully insured market. In addition, among the 579 companies that filed with the NAIC, 137 were excluded because of data anomalies. These 137 excluded companies are estimated to account for approximately 5 percent of the individual market and less than one percent of the group market.

² As noted above, issuers that are regulated by the Department of Managed Health Care in California are not required to file annual statements with the NAIC, and are not included in the estimates provided here.

E. Estimated Number of Rate Filings

This section of the regulatory impact assessment provides estimates of the number of filings that would be subject to review under this final rule.

1. Estimation Methods and Sources of Uncertainty

In the proposed rule, CMS estimated the total number of rate filings using data on the number of filings in 2010 made through the NAIC System for Electronic Rate and Form Filing ("SERFF"). However, not all issuers are required to file through SERFF, and CMS is required to make assumptions about the total number of filings in 2010, as well as the expected change in the number of filings between 2010 and 2011.

For the proposed rule, CMS conducted research to compile information regarding the regulatory structure in place by State and market. CMS analyzed information provided by States in their applications for rate review grants, analyzed State Department of Insurance Web sites, and surveyed State Insurance Department staff via telephone to obtain information regarding the number of licensed issuers and filings in the individual and small group markets. In its original estimate for the number of filings, CMS used ten representative States with relatively complete data to estimate the average number of filings that could be expected per State and by market. Those average values were used for all States to estimate the total number of filings in the individual and small group markets.

CMS also gathered information from State Insurance Departments to obtain data for 2008 through 2010 on the estimated number of filings processed, by market, and approval/rejection rate, stratified by the magnitude of the increase. Separately CMS received from the NAIC an extract showing the final disposition for all comprehensive major medical filings in SERFF for the first three quarters of calendar year 2010, by market type. This information was used to estimate the total number of filings in 2010 received and processed by the 49 States and the District of Columbia which use SERFF.

Another SERFF extract provided the number of comprehensive major medical filings filed for 2009 by 31 States. All 19 States that did not use the field "market type" were excluded from the extract. Using the data pertaining to the 31 States included in the 2009 data, CMS estimated the proportion of filings submitted by quarter, and used that distribution, along with the 2010 data, to project the number of filings for all

States using SERFF for the 4th quarter of 2010. The increase in the number of filings from 2009 to 2010, by State and market, was added to the 2010 estimates to trend the number of filings forward to 2011. CMS has determined that there is insufficient data to estimate the number of rate filings beyond 2011.

For this final rule, in addition to reviewing the 2010 SERFF data, CMS reviewed data on the number of rate filings included in the grant reports submitted by the States to CMS for the 4th quarter of 2010. Since this is data directly reported by the States to CMS, we believe that this is more reliable than what is reported in SERFF, which contains data from the health insurance issuers. There were 26 States for which both SERFF and the grant reports contained the number of rate filings for the fourth quarter of 2010. In comparing the numbers, the numbers of rate filings in the grant reports were higher than the SERFF numbers by 26 percent.

Although we did not have the numbers for all the States, the data for the 26 States is a sufficient representative sample because it is statistically significant and it reflects a representative cross-section of the set of different types of State filing authority. Accordingly, based on the grant reports data, we increased the rate filing estimates of the proposed rule by 26 percent for this final rule.

Although there is some uncertainty concerning the number of filings in 2011, a much larger source of uncertainty is uncertainty about the number of filings that will have proposed rate increases greater than or equal to 10 percent. Data on rate requests made by issuers are available from a handful of States, and CMS has used these data to estimate the proportion of rate filings with requested rate increases of 10 percent or greater. However, given the small number of States for which data is available, there is substantial uncertainty about the number of filings in 2010 with proposed rate increases that are greater than or equal to 10 percent. Further, even if CMS had precise data on the distribution of rate increase requests in 2010, it is unclear to what extent that distribution might change in 2011 as a result of this final rule. Given the combination of data imperfections and limitations and behavioral uncertainties, CMS has chosen to provide a range of estimates, based on a range of assumptions.

2. Estimated Number of Rate Filings Meeting or Exceeding the Threshold and Subject to Review

Twenty-five States require issuers to use the NAIC System for Electronic Rate and Form Filing (SERFF) and many issuers also use SERFF for filings in States that have no SERFF requirement. Based on the number of SERFF filings from 31 States for the first three quarters of 2010 and the 2010 4th quarter number of rate filings in both SERFF and the grant reports, CMS estimates a range of rate filings from 4,580 to 5,059 in the individual and small group markets for all States for all of 2010.

The total number of filings in 2011 is expected to be larger than the number of filings in 2010 in part due to an increased number of issuers required to file and additional filings to meet the justification requirements.³ Based on actuarial estimates using data from 2009 and 2010, CMS estimates that the number of 2011 rate filings will be in the range of 6,121 to 7,343 (see Table 3).

Issuers are not required to submit Preliminary Justifications for their grandfathered enrollees. The percentage of individuals covered under policies that will lose grandfathered status in the individual market is estimated to be 40 to 67 percent, according to Grandfathered Health Plan Regulation (**Federal Register**, June 17, 2010). The percentage of small group plans relinquishing their grandfathered status in the small group market is estimated to be 20 to 42 percent in 2011. CMS uses 40 percent, 54 percent, and 67 percent for the low, mid, and high estimates of the percentage of non-grandfathered rate filings in the individual market and 20 percent, 30 percent and 42 percent in the small group market.

An issuer will be required to submit a Preliminary Justification report to the Secretary and the applicable State if the rate increase is 10 percent or higher. The estimates in this regulatory impact analysis are based on this provision of the final rule.

Data from a small group of States for their individual market show the percentage of rate requests at or above 10 percent ranged from 50 percent to 72 percent during the time period 2008 to

³ According to the Kaiser Family Foundation, a number of States have already enhanced their rate review and filing process under their current authority and several other States will seek additional authority to review rates from their legislature. See *Rate Review: Spotlight on State Efforts to Make Health Insurance More Affordable*, Kaiser Family Foundation, December 2010.

2010.⁴ The fraction of enrollees in plans requesting an increase of 10 percent or greater ranged from 34 percent to 77 percent. CMS uses 50 percent, 60 percent, and 70 percent as the low, mid, and high estimates for the percentage of rate requests at or above the rate review threshold of 10 percent in the individual market, and 35 percent, 50 percent, and 75 percent for the percentage of enrollees affected.

Data on rate requests in the small group market are available from three

States (Colorado and Oregon, data for 2009 and 2010, and Minnesota, 2007 through 2010).⁵ On average, approximately 35 percent of rate requests were for 10 percent or greater, and with one exception, in each State and year combination, between 20 percent and 40 percent of rate requests were above that threshold. CMS uses 20 percent, 30 percent, and 40 percent for the low, medium, and high-range estimates of the percentage of rate requests at or above the rate review

threshold of 10 percent in the small group market. For the percentage of enrollees affected in the small group market, CMS estimates 15 percent, 30 percent, and 50 percent.⁶

The following table (Table 3) shows the low, mid and high range estimates (468, 974, and 1,723) of the number of filings that will be subject to review and require the submission of a justification report because the proposed rate increase is 10 percent or greater.

TABLE 3—ESTIMATED NUMBER OF FILINGS SUBJECT TO REVIEW

	Individual	Small group	Total
Estimated number of filings for 2011:			
Low Range	1,395	4,726	6,121
Mid Range	1,571	5,162	6,733
High Range	1,746	5,597	7,343
Percent of filings subject to review (non-grandfathered):			
Low Range	40%	20%
Mid Range	54%	30%
High Range	67%	42%
Number of filings subject to review:			
Low Range	558	945	1,503
Mid Range	848	1,549	2,397
High Range	1,170	2,351	3,521
Estimated percentage of filings meeting or exceeding threshold:			
Low Range	50%	20%
Mid Range	60%	30%
High Range	70%	40%
Estimated number of filings meeting or exceeding threshold:			
Low Range	279	189	468
Mid Range	509	465	974
High Range	819	940	1,759

3. Estimated Number of Additional Filings Subject to Review if Coverage Sold Through Associations Are Subject to the Rate Review Process

In this preamble, we discuss a proposal to amend the definitions of individual and small group markets in order for individual and small group coverage sold through associations to be subject to the rate review process. While we did not make this change in the final rule, we solicit comments in the preamble on this issue and indicate that we may amend the final rule after the comment period to include individual and small group coverage sold through

associations in the rate review process. Although we did not estimate the burden of including coverage sold through associations for the PRA package or for this RIA, an estimate is provided below for purposes of soliciting comments on the potential burden of including individual and small group coverage sold through associations in the rate review process.

In reviewing data submitted by health insurance issuers to the NAIC, it is estimated that there would be 986 filings annually that would have to be submitted for individual or small group coverage sold through associations.⁷ In applying the factors for non-

grandfathered coverage (.42) and filings above the 10% threshold (.45), both of which are discussed above, this results in a total of 186 additional filings that would be subject to rate review. We further estimate that 34 percent of these filings would occur in States that require prior approval before a rate increase can be implemented, in which case the rate filings are already subject to review by a State. Accordingly, 123 additional filings above the 10% threshold would occur if coverage sold through associations were subject to the rate review process, all of which would be reviewed by CMS.

⁴ The sources for the rate increases in the individual market are: Iowa list of proposed rate increases as of October 25, 2010, http://www.iid.state.ia.us/docs/0_Multi-year%20A&H%20Rate%20Increase_PPACA%20Types.pdf; Illinois list of proposed rate increases as of September 2010, http://www.insurance.illinois.gov/Reports/special_reports/IMMHPRFR.pdf; North Carolina rate filings, <http://infoportal.ncdoi.net/filelookup.jsp?divtype=3>; Oregon list of proposed rate increases as of November 30, 2010, http://www.oregoninsurance.org/insurer/rates_forms/health_rate_filings/health-rate-filing-search.html; Pennsylvania announcement of each proposed rate increases, <http://www.pabulletin.com/secure/search.html>; and

Washington list of proposed rate increases from the State.

⁵ The sources for the rate increases in the small group market are: Colorado list of rate increases, http://www.dora.state.co.us/pls/real/Ins_RAF_Report.main; Minnesota list of final rate increases from the State; and Oregon list of proposed rate increases, http://www.oregoninsurance.org/insurer/rates_forms/health_rate_filings/health-rate-filing-search.html.

⁶ Rate filings in which each of the products covered in the filing are grandfathered plans will not be subject to the provisions of this final rule. However, in the small group market, CMS believes that most filings are made for products which are

still being actively marketed. To the extent that there are filings in the individual market that include no products which are being actively marketed, the estimates provided here of the number of filings that will be subject to review are overestimates of the true burden that will be imposed by this final rule.

⁷ The data on which this estimate is based may exclude some issuers selling association coverage in States that do not require issuers to include data on this coverage in their annual financial reports submitted to the NAIC. In addition, this estimate did not take into account data for companies that are regulated by the California Department of Managed Health Care.

We welcome comments on any aspect of this burden estimate. We also welcome any additional data on the additional number of rate filings that would occur if individual and small group coverage sold through associations is subject to the rate review process.

F. Estimated Administrative Costs Related to Rate Review Provisions

As stated earlier in this preamble, this final rule will implement the reporting requirements of section 2794, describing the type of information that will be included in the Preliminary Justification to the Secretary and the applicable State and the disclosure that will be made available to consumers on the issuer's Web site if the rate increase is found to be unreasonable. CMS has quantified the primary sources of start-up costs that issuers in the individual and small group market will incur to bring themselves into compliance with this final rule, as well as the ongoing annual costs that they will incur related to these requirements. These costs and the

methodology used to estimate them are discussed below.

In order to assess the potential administrative effect of the requirements in this final rule, CMS consulted with the NAIC and industry experts to gain insight into the tasks and level of effort required. Based on these discussions, CMS estimates that issuers will incur one-time start-up costs associated with developing teams to review the requirements in this final rule, and developing processes for capturing the necessary data (for example, automating systems). CMS estimates that issuers will also incur ongoing annual costs relating to data collection, completing the justification reports, conducting a final internal review, submitting the reports to the Secretary and applicable State, record retention, and Web site notifications.

1. One-Time Start-Up Costs

Based on discussions with NAIC and industry experts, start-up costs are estimated at \$25,000 to \$35,000 per issuer, calculated from assumptions of 125 to 175 hours at \$200 per hour

(senior actuary fee) to review the requirements for this final rule and developing processes for data collection.

2. Ongoing Costs Related to Rate Review Reporting

For each rate review reporting year, issuers offering coverage in the individual and small group markets will be required to submit a Preliminary Justification to the Secretary and applicable State prior to the implementation of a rate increase for each proposed rate increase of 10 percent or greater.

Ongoing annual costs are estimated at 6 to 16 hours per justification report at \$200 per hour or \$1,200 to \$3,200 per report. Most of the hours are for populating the justification reports with an additional hour for record retention and Web site notification.

CMS estimates that the one-time costs relating to the rate review reporting requirements in this final rule will range from \$10 million to \$15 million, and that annual costs will be between \$0.6 million and \$5.5 million per year (Table 4).

TABLE 4—ESTIMATED COSTS FOR REPORTING, RECORD RETENTION, AND WEBSITE NOTIFICATION
[Actual dollars]

Description	Total number of issuers	Total number of reports	Estimated total hours (1)	Estimated average cost per hour (2)	Estimated total cost	Estimated average cost per issuer	Estimated average cost per report
LOW RANGE ASSUMPTIONS:							
One-Time Costs	417	468	52,125	\$200	\$10,425,000	\$25,000	\$22,276
Ongoing Costs	417	468	2,808	200	561,600	1,347	1,200
Total Year One Costs	417	468	54,933	200	10,986,600	26,347	23,476
MID RANGE ASSUMPTIONS							
One-Time Costs	417	974	62,550	200	12,510,000	30,000	12,844
Ongoing Costs	417	974	10,714	200	2,142,800	5,139	2,200
Total Year One Costs	417	974	73,264	200	14,652,800	35,139	15,044
HIGH RANGE ASSUMPTIONS							
One-Time Costs	417	1,759	72,975	200	14,595,000	35,000	8,471
Ongoing Costs	417	1,759	27,568	200	5,513,600	13,222	3,200
Total Year One Costs	417	1,759	100,543	200	20,108,600	48,222	11,671

Notes: Estimated costs are stated in 2010 dollars.
(1) Estimated number of one-time start up hours and annual ongoing hours.
(2) Actuary salary/fee.

3. Estimated Costs to the States and Federal Government Related to Rate Review Provisions

Section 2794 directs the Secretary, in conjunction with the States, to establish a process for the annual review of unreasonable increases in premiums for health insurance coverage. In doing so, both the Federal Government and States will incur certain administrative costs. However, CMS estimates that the additional costs to the States will be

negligible given that the majority already conducts some level of rate review, and the costs to the Federal Government and States will be extremely small.

4. Estimated Costs to the Federal Government

States currently have primary responsibility for the review of rate increases and will continue to under this final rule. If a State does not have an Effective Rate Review Program in

place for all or some markets within the State, CMS will review rate increases that meet or exceed the 10 percent threshold and make its own determinations of whether the rate increases were excessive, unjustified, or unfairly discriminatory, or otherwise unreasonable, within those markets. This activity could be conducted with in-house resources and/or with the use of contracted services. Given the fact that, as noted above, some States do not have review authority in either the

small group or individual markets, and assuming filings are evenly distributed across markets, CMS estimates a range between 28 percent and 36 percent of the rate filings requiring review in 2011 will fall under CMS's review

responsibility. Based on these filing estimates and the necessary actuarial expertise, this rate review process would range in cost from \$0.7 million to \$5.9 million.

Table 5 describes the assumptions used in the estimates for the administrative costs to the Federal Government associated with its rate review activities.

TABLE 5—ESTIMATED ACTUARIAL RATES

Estimated actuarial rates	Low	Mid	High
Principal Actuaries	\$340.00	\$350.00	\$360.00
Support Actuaries	200.00	234.00	275.00
Actuarial Analyst	120.00	150.00	180.00
Administrative Support	80.00	100.00	120.00
Estimated time to complete average review	Average time required		
Principal Actuaries	4.25	5.50	6.75
Support Actuaries	8.50	9.50	11.00
Actuarial Analyst	12.00	14.00	15.00
Administrative Support	9.00	9.50	12.00
Actuarial Staff Hours	24.75	29.00	32.75
Total Staff Hours	33.75	38.5	44.75
	Low	Mid	High
Estimated Cost per Review	\$5,305	\$7,198	\$9,595
Number of Rate Reviews	131	321	620
Total Expected Contracting Cost	\$695,167	\$2,313,581	\$5,948,900

In addition to the costs to the Federal government of conducting rate reviews in States that do not conduct effective reviews, there will be a small, largely one-time cost to the Federal government to determine whether States are conducting effective reviews.

5. Estimated Costs to States

CMS recognizes that States have significant experience reviewing rate increases. As discussed earlier in this preamble, most States have existing Effective Rate Review Programs that will meet the requirements of this regulation in substituting for CMS' review of rate filings that meet or exceed the threshold. Rate review grants provided by CMS are expected to increase the effectiveness of State rate review processes, but are not a direct measure of the cost of this regulation.

CMS estimates that the cost burden on States will be small because most States currently conduct rate review. For these States the incremental costs and requirements of this regulation will be

minimal. Some States do not already have a rate review process or have a process that applies to only a portion of the individual and small group markets that this regulation addresses. In these States, the implementation costs to develop effective rate review processes at the State level will be offset by the rate review grants provided by CMS. However, from a Federal budget perspective, these Federal costs from grants will be largely balanced by a decrease in the Federal cost of performing reviews directly. For States not currently conducting effective rate review, there are likely a variety of factors affecting the decision to institute an effective rate review process, including the need for resources, as well as potential legislative hurdles. The rate review grants are expected to help States overcome some of these hurdles.

States with Effective Rate Review Programs will be required to report on their rate review activities to the Secretary. CMS believes that this

reporting requirement will involve minimal cost. CMS estimates that reporting information from the State to CMS will require approximately 20 minutes per filing. Based on an actuary's fee of \$200 per hour, CMS estimates an average cost per filing of \$66.60. The estimated cost of reporting the two-thirds of filings meeting or exceeding the 10 percent threshold, which are reviewed by States, is \$42,800.

G. Transfers

The final rule will likely result in lower premiums, although the magnitude of this effect is difficult to predict. To the extent that premiums are lower as a result of the final rule, this represents a transfer from insurers/ shareholders to consumers. The experience of States that engage in rate review, summarized in Table 6, suggests that the review process may result in premium increases that are lower than they would otherwise be.⁸

⁸Data provided by States on recent rate review actions from informal discussions between CMS and State Department of Insurance actuaries.

TABLE 6—STATE RATE REVIEW ACTIONS
[State filings from 2005 to 2010]

State	Market	Number of filings	Range of rate requests	Range of actual increases	Number of rate reductions
A	Individual	96	7%–40%	0%–21%	15
	Small Group	21	14%–26%	9%–22%	5
B	Individual	31	4%–30%	1%–25%	14
	Small Group	37	1%–17%	1%–17%	5
C	Combined	34	1%–32%	1%–32%	8

It is difficult, however, to draw strong conclusions from this information about the effects of additional rate review on rates because we are uncertain about insurers' behavioral response. Further, a substantial number of States currently operate effective rate review processes, and it is likely that any potential effect in these States will be less than in States that have not previously had a strong rate review process.

Although CMS did not estimate the impact of this proposed regulation on the reduction in premium rate increases, CMS estimates that comprehensive major medical premiums are \$28 billion in the individual market and \$95 billion in the small group market, for a total of \$123 billion in 2011 (Medical Loss Ratio Regulation Technical Appendix, December 1, 2010 and National Health Expenditure projection factors). The percentage of individuals covered under policies that will lose grandfathered status in the individual market is estimated to be 40 to 67 percent (Grandfathered Health Plan Regulation, June 17, 2010). The percentage of small group plans relinquishing their grandfathered status in the small group market is estimated to be 20 to 42 percent in 2011 (Grandfathered Health Plan Regulation, June 17, 2010). Thus, CMS estimates that approximately \$30 to \$59 billion of premiums will be written by issuers in the individual and small group markets to non-grandfathered subscribers. Given the magnitude of the premiums that may be affected, CMS invited comments in the proposed rule on how to calculate premium savings so as to determine whether the \$100 million threshold is met but did not receive any responses.

H. Regulatory Alternatives

Under the Executive Order, CMS is required to consider alternatives to issuing regulations and alternative regulatory approaches. CMS considers a variety of regulatory alternatives described below.

1. Establish a Lower or Higher Threshold for Rate Increase Review

Section 2794(a) requires the Secretary, in conjunction with the States to conduct an annual review of unreasonable increases in premiums. In establishing a threshold for rate increases that would be subject to review, CMS: (1) Examined national trends in rate increases and health care costs; and (2) weighed the administrative burden on issuers and States against the level of protection for consumers.

In the proposed rule, CMS proposed a threshold of 10 percent. Comments received from issuers indicated that this was too low and that a 10 percent threshold would virtually capture all proposed rate increases thereby imposing a large burden on issuers and state regulators. Consumer advocates, on the other hand, felt that the threshold was too high since there would be rate increases below 10 percent that will be unreasonable. Consumer advocates also feared that issuers could game the process by keeping their rate increases at no higher than 9.9 percent.

If CMS established a threshold lower than 10 percent, this would impose a larger burden on issuers, States, and CMS, and CMS judged that it would not yield a substantial benefit for consumers. In addition, CMS has also taken into consideration the fact that many States, as discussed below, conduct a rate review process for all rate increases without regard to the magnitude of the increase, and we expect the number of States conducting the reviews to increase. Therefore, as a practical matter, in a growing number of States, the prospect that an unreasonable increase that is also below the 10 percent threshold would be implemented without review is mitigated by the State review processes.

CMS recognizes that there may be rate increases that fall below the 10 percent threshold that are unjustified. However, given the practice of many States to review all increases, CMS considered the costs and benefits of the additional Federal resources to potentially catch unjustified or unreasonable rates versus

fairness to consumers and the additional administrative burden for insurers. CMS decided against spending additional resources to potentially catch only a small number of unreasonable rates below the threshold.

CMS also examined establishing a threshold higher than 10 percent for rate increases that would be subject to review. However, in attempting to strike the balance discussed above, CMS decided on the 10 percentage point threshold. Specifically, with a threshold higher than 10 percent, consumers would face greater exposure to rate increases that were either unjustified or excessive with no assurance that those rates were given a careful review.

2. Establish a Threshold Based on the Market Share of the Insurer

An alternative approach would have established a lower threshold for insurers with larger market share, with the justification that such insurers were more likely to be able to exert market power. However, analysis of data from a limited number of States suggested showed no evidence that larger insurers proposed higher rates of increase. Further, to the extent that market power exists in the individual market because subscribers with health problems are unable to switch to a competing insurer, this power exists equally for small companies as for large ones. As a result, CMS decided to utilize a uniform threshold for all insurers, regardless of their size.

3. Apply Rate Review Standards to the Large Group Market

As discussed in the Preamble, CMS discussed applying this final rule to the large group market as well as the individual and small group markets. Comments were received in response to the proposed rule that supported including the large group market in the rate review process. However, because of the current rate-setting practices of the large group market and States' limited authority over this segment of the market, CMS concluded that this regulation should only apply to the individual and small group markets.

4. Including Individual and Small Group Coverage Sold Through Associations in the Rate Review Process

We generally deferred in the proposed rule to the State definitions of individual and small group markets. In response to the proposed rule, we received comments indicating that, in some States, association coverage is considered to be large group coverage, resulting in individual and small group coverage sold through associations not being subject to the rate review process. We considered amending the definitions of individual market and small group market for the final rule in order to include all individual and small group coverage in the rate review process. However, since including all individual and small group coverage sold through associations in the rate review process could have a large impact on the markets in some States, we are incorporating the proposed definitions of individual market and small group market into the final rule and solicit additional comments on this issue, with the possibility of amending the final rule after receiving comments in order to include coverage sold through associations in the rate review process.

I. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies that issue a regulation to analyze options for regulatory relief of small businesses if a final rule has a significant impact on a substantial number of small entities. The RFA generally defines a "small entity" as: (1) A proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a nonprofit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000 (States and individuals are not included in the definition of "small entity"). CMS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a final rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. Small businesses are those with sizes below thresholds established by the Small Business Administration (SBA). We examined the health insurance industry in depth in the Regulatory Impact Analysis we prepared for the proposed rule on establishment of the Medicare

Advantage program (69 FR 46866, August 3, 2004). In that analysis we determined that there were few if any insurance firms underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) that fell below the size thresholds for "small" business established by the SBA.

Further, the one-time costs of this final rule are approximately \$25,000 per covered entity (regardless of size or non-profit status) and approximately \$4,000 annually in ongoing costs. Numbers of this magnitude do not remotely approach the amounts necessary to be considered a "significant economic impact" on firms with revenues of tens of millions of dollars (usually hundreds of millions or billions of dollars annually). Accordingly, we have determined, and certify, that this final rule will not have a significant economic impact on a substantial number of small entities and that a regulatory flexibility analysis is not required.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a final rule may have a significant economic impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. This final rule will not affect small rural hospitals. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

J. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any final rule that includes a Federal mandate that could result in expenditure in any one year by State, local or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold level is approximately \$136 million.

UMRA does not address the total cost of a final rule. Rather, it focuses on certain categories of cost, mainly those "Federal mandate" costs resulting from: (1) Imposing enforceable duties on State, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs.

This final rule includes no mandates on State, local, or tribal governments.

Under the final rule, issuers would be required to submit rate justification reports for rate increases of 10 percent or greater directly to CMS. A State may voluntarily choose to use its existing rate review process, if deemed an Effective Rate Review Program, to make a determination as to whether a rate increase is unreasonable. If a State chooses to review the rate increase, the State would be required to submit to CMS the final determination and an explanation of its analysis. However, if a State chooses not to do so, CMS would review a rate increase subject to review to determine whether it is unreasonable. Thus, the law and this regulation do not impose an unfunded mandate on States. However, consistent with policy embodied in UMRA, this final rule has been designed to be the least burdensome alternative for State, local and tribal governments, and the private sector while achieving the objectives of the Affordable Care Act.

K. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. In CMS' view, while the requirements proposed in this final rule would not impose substantial direct costs on State and local governments, this final rule has federalism implications due to direct effects on the distribution of power and responsibilities among the State and Federal governments relating to determining the reasonableness of rate increases for coverage that State-licensed health insurance issuers offer in the individual and small group markets.

CMS recognizes that there are federalism implications with regard to CMS' evaluation of Effective Rate Review Programs and its subsequent review of rate increases. Under Subpart C of this final rule, CMS outlines those criteria that States would have to meet in order to be deemed to have an Effective Rate Review Program. If CMS determines that a State does not meet those criteria, then CMS would review a rate increase subject to review to determine whether it is unreasonable. If a State does meet the criteria, then CMS would adopt that State's determination of whether a rate increase is unreasonable.

States would continue to apply State law requirements regarding rate and policy filings. State rate review processes that are more stringent than

the Federal requirements likely would be deemed effective and satisfy the requirements under this final rule. Accordingly, States have significant latitude to impose requirements with respect to health insurance issuers that are more restrictive than the Federal law.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the States, CMS has engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners (NAIC), participating in a NAIC workgroup on rate reviews and consulting with State insurance officials on an individual basis.

Throughout the process of developing this final rule, CMS has attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide uniform protections to consumers in every State. By doing so, it is CMS' view that it has complied with the requirements of Executive Order 13132. Under the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to this regulation, CMS certifies that the Center for Consumer Information and Insurance Oversight has complied with the requirements of Executive Order 13132 for the attached final rule in a meaningful and timely manner.

List of Subjects in 45 CFR Part 154

Administrative practice and procedure, Claims, Health care, Health insurance, Health plans, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR Subtitle A, Subchapter B, by adding part 154 to read as follows:

PART 154—HEALTH INSURANCE ISSUER RATE INCREASES: DISCLOSURE AND REVIEW REQUIREMENTS

Subpart A—General Provisions

- Sec.
154.101 Basis and scope.
154.102 Definitions.
154.103 Applicability.

Subpart B—Disclosure and Review Provisions

- 154.200 Rate increases subject to review.
154.205 Unreasonable rate increases.

- 154.210 Review of rate increases subject to review by CMS or by a State.
154.215 Submission of disclosure to CMS for rate increases subject to review.
154.220 Timing of providing the Preliminary Justification.
154.225 Determination by CMS or a State of an unreasonable rate increase.
154.230 Submission and posting of Final Justifications for unreasonable rate increases.

Subpart C—Effective Rate Review Programs

- 154.301 CMS's determinations of Effective Rate Review Programs.

Authority: Section 2794 of the Public Health Service Act (42 USC 300gg–94).

Subpart A—General Provisions

§ 154.101 Basis and scope.

(a) *Basis.* This part implements section 2794 of the Public Health Service (PHS) Act.

(b) *Scope.* This part establishes the requirements for health insurance issuers offering health insurance coverage in the small group or individual markets to report information concerning unreasonable rate increases to the Centers for Medicare & Medicaid Services (CMS). This part further establishes the process by which it will be determined whether the rate increases are unreasonable rate increases as defined in this part.

§ 154.102 Definitions.

As used in this part:

CMS means the Centers for Medicare & Medicaid Services.

Effective Rate Review Program means a State program that CMS has determined meets the requirements set forth in § 154.301(a) and (b) for the relevant market segment in the State.

Federal medical loss ratio standard means the applicable medical loss ratio standard for the State and market segment involved, determined under subpart B of 45 CFR part 158.

Health insurance coverage has the meaning given the term in section 2791(b)(1) of the PHS Act.

Health insurance issuer has the meaning given the term in section 2791(b)(2) of the PHS Act.

Individual market has the meaning given the term under the applicable State's rate filing laws, except that where State law does not define the term, it has the meaning given in section 2791(e)(1)(A) of the PHS Act.

Product means a package of health insurance coverage benefits with a discrete set of rating and pricing methodologies that a health insurance issuer offers in a State.

Rate increase means any increase of the rates for a specific product offered in the individual or small group market.

Rate increase subject to review means a rate increase that meets the criteria set forth in § 154.200.

Secretary means the Secretary of the Department of Health and Human Services.

Small group market has the meaning given under the applicable State's rate filing laws, except that where State law does not define the term, it has the meaning given in section 2791(e)(5) of the PHS Act; provided, however, that for the purpose of this definition, "50" employees is substituted for "100" employees in the definition of "small employer" under section 2791(e)(4).

State has the meaning given the term in section 2791(d)(14) of the PHS Act.

Unreasonable rate increase means:

(1) When CMS is conducting the review required by this part, a rate increase that CMS determines under § 154.205 is:

- (i) An excessive rate increase;
(ii) An unjustified rate increase; or
(iii) An unfairly discriminatory rate increase.

(2) When CMS adopts the determination of a State that has an Effective Rate Review Program, a rate increase that the State determines is excessive, unjustified, unfairly discriminatory, or otherwise unreasonable as provided under applicable State law.

§ 154.103 Applicability.

(a) *In general.* The requirements of this part apply to health insurance issuers offering health insurance coverage in the individual market and small group market.

(b) *Exceptions.* The requirements of this part do not apply to grandfathered health plan coverage as defined in 45 CFR § 147.140, or to excepted benefits as described in section 2791(c) of the PHS Act.

Subpart B—Disclosure and Review Provisions

§ 154.200 Rate increases subject to review.

(a) A rate increase filed in a State on or after September 1, 2011, or effective on or after September 1, 2011, in a State that does not require a rate increase to be filed, is subject to review if:

(1) The rate increase is 10 percent or more, applicable to a 12-month period that begins on September 1, as calculated under paragraph (c) of this section; or

(2) The rate increase meets or exceeds a State-specific threshold applicable to

a 12-month period that begins on September 1, as calculated under paragraph (c) of this section, determined by the Secretary. In establishing a State-specific threshold, the Secretary shall consult with the State and may consider relevant information provided by other interested parties. A State-specific threshold shall be based on factors impacting rate increases in a State to the extent that data relating to such State-specific factors is available.

(b) The Secretary will publish a notice no later than June 1 of each year concerning whether a threshold under paragraph (a)(1) or (2) of this section applies to a State; except that, with respect to the 12-month period that begins on September 1, 2011, the threshold under paragraph (a)(1) of this section applies.

(c) A rate increase meets or exceeds the applicable threshold set forth in paragraph (a) of this section if the average increase for all enrollees weighted by premium volume meets or exceeds the applicable threshold.

(d) If a rate increase that does not otherwise meet or exceed the threshold under paragraph (c) of this section meets or exceeds the threshold when combined with a previous increase or increases during the 12-month period preceding the date on which the rate increase would become effective, then the rate increase must be considered to meet or exceed the threshold and is subject to review under § 154.210, and such review shall include a review of the aggregate rate increases during the applicable 12-month period.

§ 154.205 Unreasonable rate increases.

(a) When CMS reviews a rate increase subject to review under § 154.210(a), CMS will determine that the rate increase is an unreasonable rate increase if the increase is an excessive rate increase, an unjustified rate increase, or an unfairly discriminatory rate increase.

(b) The rate increase is an excessive rate increase if the increase causes the premium charged for the health insurance coverage to be unreasonably high in relation to the benefits provided under the coverage. In determining whether the rate increase causes the premium charged to be unreasonably high in relationship to the benefits provided, CMS will consider:

(1) Whether the rate increase results in a projected medical loss ratio below the Federal medical loss ratio standard in the applicable market to which the rate increase applies, after accounting for any adjustments allowable under Federal law;

(2) Whether one or more of the assumptions on which the rate increase

is based is not supported by substantial evidence; and

(3) Whether the choice of assumptions or combination of assumptions on which the rate increase is based is unreasonable.

(c) The rate increase is an unjustified rate increase if the health insurance issuer provides data or documentation to CMS in connection with the increase that is incomplete, inadequate or otherwise does not provide a basis upon which the reasonableness of an increase may be determined.

(d) The rate increase is an unfairly discriminatory rate increase if the increase results in premium differences between insureds within similar risk categories that:

(1) Are not permissible under applicable State law; or

(2) In the absence of an applicable State law, do not reasonably correspond to differences in expected costs.

§ 154.210 Review of rate increases subject to review by CMS or by a State.

(a) Except as provided in paragraph (b) of this section, CMS will review a rate increase subject to review to determine whether it is unreasonable, as required by this part.

(b) CMS will adopt a State's determination of whether a rate increase is an unreasonable rate increase, if the State:

(1) Has an Effective Rate Review Program as described in § 154.301; and

(2) The State provides to CMS, on a form and in a manner prescribed by the Secretary, its final determination of whether a rate increase is unreasonable, which must include a brief explanation of how its analysis of the relevant factors set forth in § 154.301(a)(3) caused it to arrive at that determination, within five business days following the State's final determination.

(c) CMS will post and maintain on its Web site a list of the States with market segments that meet the requirements of paragraph (b) of this section.

§ 154.215 Submission of disclosure to CMS for rate increases subject to review.

(a) For each rate increase subject to review, a health insurance issuer must submit a Preliminary Justification for each product affected by the increase on a form and in the manner prescribed by the Secretary.

(b) The Preliminary Justification must consist of the following Parts:

(1) Rate increase summary (Part I), as described by paragraph (e) of this section;

(2) Written description justifying the rate increase (Part II), as described by paragraph (f) of this section; and

(3) When CMS is reviewing the rate increase under § 154.210(a), rate filing documentation (Part III), as described by paragraph (g) of this section.

(c) A health insurance issuer must complete and submit Parts I and II of the Preliminary Justification described in paragraphs (b)(1) and (2) of this section to CMS and, as long as the applicable State accepts such submissions, to the applicable State for any rate increase subject to review. If a rate increase subject to review is for a product offered in the individual market or small group market and CMS is reviewing the rate increase under § 154.210(a), then the health insurance issuer must also complete and submit Part III of the Preliminary Justification described in paragraph (b)(3) of this section to CMS only.

(d) The health insurance issuer may submit a single, combined Preliminary Justification for rate increases subject to review affecting multiple products, if the claims experience of all products has been aggregated to calculate the rate increases and the rate increases are the same across all products.

(e) Content of rate increase summary (Part I): The rate increase summary must include the following as determined appropriate by the Secretary:

(1) Historical and projected claims experience;

(2) Trend projections related to utilization, and service or unit cost;

(3) Any claims assumptions related to benefit changes;

(4) Allocation of the overall rate increase to claims and non-claims costs;

(5) Per enrollee per month allocation of current and projected premium; and

(6) Three year history of rate increases for the product associated with the rate increase.

(f) Content of written description justifying the rate increase (Part II): The written description of the rate increase must include a simple and brief narrative describing the data and assumptions that were used to develop the rate increase and include the following:

(1) Explanation of the most significant factors causing the rate increase, including a brief description of the relevant claims and non-claims expense increases reported in the rate increase summary; and

(2) Brief description of the overall experience of the policy, including historical and projected expenses, and loss ratios.

(g) Content of rate filing documentation (Part III): (1) The rate filing documentation must be sufficient for CMS to conduct an examination satisfying the requirements of

§ 154.301(a)(3) and (4) and determine whether the rate increase is an unreasonable increase. Instructions concerning the requirements for the rate filing documentation will be provided in guidance issued by CMS.

(2) If the health insurance issuer is also required to submit a rate filing to a State in connection with the rate increase under State law, CMS will accept a copy of the filing provided that the filing includes all of the information described in paragraph (g)(1) of this section.

(h) If the level of detail provided by the issuer for the information under paragraph (g) of this section does not provide sufficient basis for CMS to determine whether the rate increase is an unreasonable rate increase, CMS will request the additional information necessary to make its determination. The health insurance issuer must provide the requested information to CMS within 10 business days following its receipt of the request.

(i) Posting of the disclosure on the CMS Web site: (1) CMS promptly will make available to the public on its Web site the information contained in Parts I and II of each Preliminary Justification.

(2) CMS will make available to the public on its Web site the information contained in Part III of each Preliminary Justification that is not a trade secret or confidential commercial or financial information as defined in CMS's Freedom of Information Act regulations, 45 CFR 5.65.

(3) CMS will include a disclaimer on its Web site with the information made available to the public that explains the purpose and role of the Preliminary Justification.

(j) CMS will include information on its Web site concerning how the public can submit comments on the proposed rate increases that CMS reviews.

§ 154.220 Timing of providing the Preliminary Justification.

A health insurance issuer must submit a Preliminary Justification for all rate increases subject to review that are filed in a State on or after September 1, 2011, or effective on or after September 1, 2011 in a State that does not require the rate increase subject to review to be filed, as follows:

(a) If a State requires that a proposed rate increase be filed with the State prior to the implementation of the rate, the health insurance issuer must submit to CMS and the applicable State the Preliminary Justification on the date on which the health insurance issuer submits the proposed rate increase to the State.

(b) For all other States, the health insurance issuer must submit to CMS and the State the Preliminary Justification prior to the implementation of the rate increase.

§ 154.225 Determination by CMS or a State of an unreasonable rate increase.

(a) When CMS receives a Preliminary Justification for a rate increase subject to review and CMS reviews the rate increase under § 154.210(a), CMS will make a timely determination whether the rate increase is an unreasonable rate increase.

(1) CMS will post on its Web site its final determination and a brief explanation of its analysis, consistent with the form and manner prescribed by the Secretary under § 154.210(b)(2), within five business days following its final determination.

(2) If CMS determines that the rate increase is an unreasonable rate increase, CMS will also provide its final determination and brief explanation to the health insurance issuer within five business days following its final determination.

(b) If a State conducts a review under § 154.210(b), CMS will adopt the State's determination of whether a rate increase is unreasonable and post on the CMS Web site the State's final determination described in § 154.210(b)(2).

(c) If a State determines that the rate increase is an unreasonable rate increase and the health insurance issuer is legally permitted to implement the unreasonable rate increase under applicable State law, CMS will provide the State's final determination and brief explanation to the health insurance issuer within five business days following CMS's receipt thereof.

§ 154.230 Submission and posting of Final Justifications for unreasonable rate increases.

(a) If a health insurance issuer receives from CMS a final determination by CMS or a State that a rate increase is an unreasonable rate increase, and the health insurance issuer declines to implement the rate increase or chooses to implement a lower increase, the health insurance issuer must submit to CMS timely notice that it will not implement the rate increase or that it will implement a lower increase on a form and in the manner prescribed by the Secretary.

(b) If a health insurance issuer implements a lower increase as described in paragraph (a) of this section and the lower increase does not meet or exceed the applicable threshold under § 154.200, such lower increase is not subject to this part. If the lower

increase meets or exceeds the applicable threshold, the health insurance issuer must submit a new Preliminary Justification under this part.

(c) If a health insurance issuer implements a rate increase determined by CMS or a State to be unreasonable, within the later of 10 business days after the implementation of such increase or the health insurance issuer's receipt of CMS's final determination that a rate increase is an unreasonable rate increase, the health insurance issuer must:

(1) Submit to CMS a Final Justification in response to CMS's or the State's final determination, as applicable. The information in the Final Justification must be consistent with the information submitted in the Preliminary Justification supporting the rate increase; and

(2) Prominently post on its Web site the following information on a form and in the manner prescribed by the Secretary:

(i) The information made available to the public by CMS and described in § 154.215(i);

(ii) CMS's or the State's final determination and brief explanation described in § 154.225(a) and § 154.210(b)(2), as applicable; and

(iii) The health insurance issuer's Final Justification for implementing an increase that has been determined to be unreasonable by CMS or the State, as applicable.

(3) The health insurance issuer must continue to make this information available to the public on its Web site for at least three years.

(d) CMS will post all Final Justifications on the CMS Web site. This information will remain available to the public on the CMS Web site for three years.

Subpart C—Effective Rate Review Programs

§ 154.301 CMS's determinations of Effective Rate Review Programs.

(a) *Effective Rate Review Program.* In evaluating whether a State has an Effective Rate Review Program, CMS will apply the following criteria for the review of rates for the small group market and the individual market, and also, as applicable depending on State law, the review of rates for different types of products within those markets:

(1) The State receives from issuers data and documentation in connection with rate increases that are sufficient to conduct the examination described in paragraph (a)(3) of this section.

(2) The State conducts an effective and timely review of the data and

documentation submitted by a health insurance issuer in support of a proposed rate increase.

(3) The State's rate review process includes an examination of:

(i) The reasonableness of the assumptions used by the health insurance issuer to develop the proposed rate increase and the validity of the historical data underlying the assumptions; and

(ii) The health insurance issuer's data related to past projections and actual experience.

(4) The examination must take into consideration the following factors to the extent applicable to the filing under review:

(i) The impact of medical trend changes by major service categories;

(ii) The impact of utilization changes by major service categories;

(iii) The impact of cost-sharing changes by major service categories;

(iv) The impact of benefit changes;

(v) The impact of changes in enrollee risk profile;

(vi) The impact of any overestimate or underestimate of medical trend for prior year periods related to the rate increase;

(vii) The impact of changes in reserve needs;

(viii) The impact of changes in administrative costs related to programs that improve health care quality;

(ix) The impact of changes in other administrative costs;

(x) The impact of changes in applicable taxes, licensing or regulatory fees;

(xi) Medical loss ratio; and

(xii) The health insurance issuer's capital and surplus.

(5) The State's determination of whether a rate increase is unreasonable is made under a standard that is set forth in State statute or regulation.

(b) *Public disclosure and input.* In addition to satisfying the provisions in paragraph (a) of this section, a State with an Effective Rate Review Program must provide access from its Web site to the Parts I and II of the Preliminary Justifications of the proposed rate increases that it reviews and have a

mechanism for receiving public comments on those proposed rate increases.

(c) CMS will determine whether a State has an Effective Rate Review Program for each market based on information available to CMS that a rate review program meets the criteria described in paragraphs (a) and (b) of this section.

(d) CMS reserves the right to evaluate from time to time whether, and to what extent, a State's circumstances have changed such that it has begun to or has ceased to satisfy the criteria set forth in paragraphs (a) and (b) of this section.

Dated: May 3, 2011.

Donald M. Berwick,
Administrator, Centers for Medicare & Medicaid Services.

Approved: May 18, 2011.

Kathleen Sebelius,
Secretary, Department of Health and Human Services.

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