

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 154

[OCIO-9999-P; Docket No. HHS-OS-2010-0029]

RIN 0950-AA03

Rate Increase Disclosure and Review

AGENCY: Office of Consumer Information and Insurance Oversight (OCIO), Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document contains proposed regulations implementing the rules for health insurance issuers regarding the disclosure and review of unreasonable premium increases under section 2794 of the Public Health Service Act. The proposed rule would establish a rate review program to ensure that all rate increases that meet or exceed an established threshold are reviewed by a State or HHS to determine whether the rate increases are unreasonable.

DATES: Send your comments on or before February 22, 2011.

ADDRESSES: All comments will be made available to the public.

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

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

You may submit comments using any of the following methods (please choose only one of the ways listed):

- *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the "More Search Options" tab.

- *Mail.* You may mail written comments to the following address
ONLY: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIO-9999-P, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201. Please allow sufficient time for mailed comments to be received before the close of the comment period.

- *Hand or Courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to the following address: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIO-9999-P, 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 OCIO 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.)

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

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the "ADDITIONAL INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

For questions concerning this proposed rule, contact Sally McCarty, Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, by phone at (301) 492-4489 OR by e-mail at ratereview@hhs.gov.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. 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 also be 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 p.m. To schedule an

appointment to view public comments, phone 1-800-743-3951.

Table of Contents

I. Background
II. Provisions of the Proposed Rule
A. Introduction and Overview
B. Definitions (§ 154.102)
C. Applicability (§ 154.103)
D. Rate Increases Subject to Review (§ 154.200)
E. Review of Rate Increases Subject to Review by HHS or by a State (§ 154.210)
F. Effective Rate Review Program (§ 154.301)
G. Unreasonable Rate Increases
H. Issuer Disclosure Required Under Part 154
III. Collection of Information Requirements
IV. Response to Comments
V. Regulatory Impact Analysis

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.

The Department of Health and Human Services (HHS or the Department) is issuing regulations in several phases in order to implement revisions to the PHS Act made by the Affordable Care Act. Most of the previous regulations were issued jointly with the Departments of Labor and the Treasury. A request for comments relating to the medical loss ratio (MLR) provisions of PHS Act section 2718 was published in the **Federal Register** on April 14, 2010 (75 FR 19297) (notice, or request for comments). A request for comments relating to the premium review provisions of PHS Act section 2794 was also published by HHS in the **Federal Register** on April 14, 2010 (75 FR 19335) (notice, or request for comments). Additionally, a series of interim final regulations were published earlier this year implementing PHS Act provisions added by the Affordable Care Act. Specifically, interim final rules were published implementing (1) section 2714 (requiring dependent coverage of children to age 26) (75 FR 27122 (May 13, 2010)); (2) section 1251 of the Affordable Care Act (relating to status as a grandfathered health plan) (75 FR 34538 (June 17, 2010)); (3) sections 2704 (prohibiting preexisting condition exclusions), 2711

(regarding lifetime and annual dollar limits on benefits), 2712 (regarding restrictions on rescissions), and 2719A (regarding patient protections) (75 FR 37188 (June 28, 2010)); (4) section 2713 (regarding preventive health services) (75 FR 41726 (July 19, 2010)); (5) section 2719 (regarding internal claims and appeals and external review processes) (75 FR 43330 (July 23, 2010)). HHS published interim final regulations implementing PHS Act section 2718 (regarding medical loss ratio (75 FR 74864 (December 1, 2010)). HHS, Department of Labor, and Department of the Treasury also published an amendment to the interim final regulations relating to status as a grandfathered health plan (regarding change in health insurance issuers) in the **Federal Register** on November 17, 2010 (75 FR 70114). The Departments have also published sub-regulatory guidance regarding various issues related to the implementation of the Affordable Care Act, available at <http://www.dol.gov/ebsa> and <http://www.hhs.gov/ociio>.

These proposed regulations are being published to implement section 2794 of the PHS Act, relating to the disclosure and review of unreasonable premium increases.¹

II. Provisions of the Proposed Rule

A. Introduction and Overview

Section 1003 of the Affordable Care Act adds a new PHS Act section 2794 which 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.” The statute provides that this process shall require health insurance issuers to submit to the Secretary and the applicable State a justification for an unreasonable premium increase prior to the implementation of the increase.

The review process required under section 2794 does not preempt or supplant any existing State laws or processes governing the review of insurance premiums, including any State authority to prevent the implementation of unreasonable rates. Many States’ laws already provide that rates may not be approved, or may not remain in effect, if they are excessive or unreasonable in relation to the benefits provided or fail to satisfy other statutory standards. Specifically, our review of State law indicates that 43 of the 50 States currently have some rate review

process, in either the individual or small group markets, or both.

This proposed regulation recognizes the traditional role of the States in regulating insurance rates and builds on existing State-based rate review processes. In circumstances where HHS is reviewing rates rather than a State, which we believe will be a minority of States that have not yet established effective rate review programs as discussed below, a determination by HHS that a rate increase is “unreasonable” under section 2794 would not prevent any health insurance issuer from implementing a rate increase permitted by State law. In this regard, this proposed regulation preserves the opportunity for insurers to implement a proposed rate that is consistent with State law. Moreover, the process established by this proposed regulation would not result in any delay in an issuer’s ability to implement a proposed rate increase. In other words, the requirements of Section 2794 only supplement and complement, rather than supplant, and do not interfere with, existing State laws and processes for rate review.

Section 2794 of the PHS Act directs the Secretary, in conjunction with the States, to establish a process for the annual review of unreasonable increases in “premiums.” “Premium” is the final amount charged to a specific insured. For those States that currently review proposed increases in “premiums,” it is the underlying rates and methods that are the subject of the actuarial review conducted by these States.

To determine rates for a specific insurance product, the issuer must estimate future claims costs in connection with that product and then the revenue needed to pay anticipated claims and non-claims expenses, such as administrative expenses including profits. The costs that will be incurred and the revenue that will be received are not known at the time the rate is established (indeed, the number of people that will be covered by the product is not known), so the rates must be based on an actuarial estimate of these costs and of the non-claims expenses. It is these estimates, along with the methodology used to determine them, that are the subject of the actuarial review conducted by States that have authority to review premium or rate increases.

Once the overall amount of revenue needed is established, the premium that will be charged to specific insureds is determined. Generally, the premium charged will vary depending on characteristics such as age, geography, and in the individual market in many

States, health status. It will also vary based on choices made by the insured, such as the amount of deductibles and co-pays. The criteria that may be used and the differences in premium that may be charged are determined by State law.

This proposed regulation, therefore, provides a process for the review of unreasonable rate increases, based upon the practice in States that conduct effective reviews of the cost of health insurance coverage.

Section 2794 of the PHS Act does not define what makes a rate increase “unreasonable,” nor does it specify the process that should be used for determining whether a particular rate increase is unreasonable (requiring that a review be conducted and a justification submitted). Therefore, this proposed regulation provides a definition of an “unreasonable” rate increase, and outlines a process that would be used by HHS when reviewing rate increases to determine which rates are subject to review and among them which are “unreasonable.”

We considered two types of processes that arguably could satisfy the requirement in 2794 that unreasonable rates be reviewed. One would establish, by regulation, a standard of unreasonableness, based on some criteria other than an actuarial standard or actual review. For example, any rate increase exceeding the average increase for similar products during the previous year, or any rate increase exceeding a rate of inflation of medical costs by a specific amount, could be deemed to be unreasonable. Under this approach, any rate increase over a pre-determined percentage would be considered “unreasonable” and therefore subject to review. However, while consumers may view any large increase in the cost of their health insurance coverage to be “unreasonable,” it is not possible to know whether an increase is “unreasonable” from an actuarial standpoint until the proposed increase, and the underlying assumptions, have been the subject of actuarial analysis. Moreover, while such an approach may be relatively easy to administer, for the reasons stated above it almost certainly would label as “unreasonable” rate increases that are not unreasonable from an actuarial standpoint. This point was made in numerous comments received in response to the Request for Comments published on April 14, 2010 in the **Federal Register** (75 FR 19335). Those comments suggest that HHS should not establish a definition of an unreasonable rate increase by, for example, providing that all rate increases greater than a specified

¹ There are two sections numbered 2794 in the Public Health Service Act. The Section 2794 that is the basis for this rule is entitled “Ensuring That Consumers Get Value For Their Dollars.”

percentage would be deemed to be unreasonable.

In addition, this “literal” reading under which rates are deemed “unreasonable” at the outset, in the absence of review, would make any “review” process meaningless, as the outcome of any review (that is, whether the rate was “unreasonable”) would have been pre-determined.

This proposed regulation instead proposes an alternative approach that is consistent with the language of section 2794; is more narrowly focused on what we interpret to be the purpose of that section; and would not involve the anomaly of “pre-determining” the reasonableness of a rate before it has been reviewed. Under this approach, if a proposed rate increase equals or exceeds a defined threshold, it would be considered “subject to review.” The review process would then determine if the increase is, in fact, unreasonable. This approach interprets the statutory “process” for reviewing unreasonable rate increases as a process under which rates that may ultimately be determined to be unreasonable are reviewed. Under this interpretation, identifying potentially unreasonable rates for review is reasonably an element of a broader process for the review of proposed rate increases.

Rates above the threshold would not be deemed or otherwise determined to be unreasonable in advance of this review. As discussed below, for rate increases filed in a State on or after July 1, 2011, or effective on or after July 1, 2011 in a State that does not require a rate increase to be filed, the threshold for whether rates are subject to review would be whether the average weighted increase in the rate filing, alone or in combination with prior increases in the preceding 12 month period, is 10 percent or more.

In establishing the 10 percent threshold for determining which rates are subject to review, HHS has balanced the wide range of available data on rate and medical trend increases. HHS reviewed available data and literature on insurance rate increases in States and general trends in health care costs. HHS reviewed each State’s applicable Web site, and determined that the information related to rate trends posted on these Web sites is limited. Our review of the limited data available suggests that the majority of increases in the individual market exceeded 10 percent each year for the past 3 years.

These yearly increases significantly exceed some national measures of medical cost inflation, such as the medical component of the Consumer Price Index, whose inflation has

typically ranged from 3.7 percent to 4.4 percent. The Centers for Medicare and Medicaid Services’ National Health Expenditures (NHE) data is another measure of health care cost trends based on overall national health care spending. The five most recent years of available NHE data suggest that overall health care expenditures have increased at an annual rate between 4.4 percent to 6.9 percent. Some commenters suggested using these indices as thresholds for a review of rate increases. Another national index, the Standard & Poor’s Healthcare Economic Commercial Index, also measures insurance rate trends. The S & P Index measures trends in provider claims costs, which encompasses both unit cost and utilization changes; the trend in that index from September 2009 to September 2010 was 8.5 percent.

The 10 percent threshold established in this regulation exceeds these major indices and in doing so balances industry concerns that any threshold would be over-inclusive with the competing concern that it would subject to review too few rates that may be unreasonable. As we discuss below, when better and more specific data on trends in insurance rates in individual States can be collected, State-specific thresholds would be established.

This approach does not provide for the review of every proposed rate increase, no matter how small, to determine whether it is unreasonable. We recognize that the choice of any threshold makes it inevitable that unreasonable rate increases below the threshold will not be reviewed, and that a proposed increase of less than 10 percent would be unreasonable if the actuarial assumptions underlying the increase were invalid or unreasonable. In proposing this approach, HHS also has 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. We expect the number of States conducting such reviews to increase in light of additional resources provided under the rate review grants and passage of State legislation. Therefore, as a practical matter, in a growing number of States, there is even less likelihood that an unreasonable increase below the threshold would be implemented.

In this regulation, HHS proposes an approach that balances the regulatory burdens that would be imposed on both the agency and the industry if every rate increase, no matter how small, were to be reviewed for unreasonableness against the potential harm to consumers should a small, but unreasonable,

increase not be reviewed and the issuer not be required to provide a final justification for the increase. We invite comments on whether 10 percent is a reasonable threshold to apply in determining which rate increases will be subject to review.

In establishing an initial 10 percent threshold for whether a rate increase is subject to review, as discussed below, HHS recognizes that rates, underlying costs, and health care trends vary from State to State. Many factors influence the magnitude and frequency of increases in the States, and a single, national filing threshold does not reflect all of the local variations. As a consequence, HHS would propose, for future calendar years, to establish State-specific thresholds for each future calendar year by September 15th of the prior year. In determining each State-specific threshold, HHS would consider the State-specific data submitted for each rate increase subject to review, and also the State-specific data received by HHS from those States that have received “premium review grants” under section 2794(c) of the PHS Act. To the extent that a State insurance regulator has other data that could serve as the basis for a State-specific threshold, that would be considered as well.

As discussed below, the State-specific threshold would be based on the same analysis used to develop the initial 10 percent threshold, but would be based on data from the specific State, rather than the national data we analyzed in selecting the proposed 10 percent figure.

In response to the Request for Comments, many commenters also suggested that the rate review process should not apply to rate increases in the large group market. Currently, our review of State law indicates that only 18 States have authority to review rates for all or part of the large group market. Applying this regulation to the large group market would result in a process that is not closely aligned with most State processes upon which the regulation is modeled. In addition, many issuers are not accustomed to submitting proposed rate increases for review in this market. Finally, purchasers in the large group market have greater leverage than those in the individual and small group markets, and therefore may be better able to avoid imposition of unreasonable rate increases. For these reasons, under this proposed regulation, rates in the large group market would not be subject to the rate review process we are proposing. HHS solicits specific comments on whether, in the future, if rate increases in the large group market were subject to a review process under

section 2794, if that process should differ from the process provided for in this proposed regulation for the individual and small group markets.

In recognition of the primary role States have in reviewing rates today, HHS would defer to the definitions used under applicable State rate filing laws when determining whether a rate filing relates to health insurance coverage offered in the individual market, small group market, or large group market, where such laws differ from the definitions of these terms in the PHS Act. HHS believes that deferring to the definitions employed in State rate filing laws ensures that the rate review process under this proposed regulation would not disrupt current State rate filing and review practices; however, we are soliciting public comment on alternative approaches. We note that this is solely for rate filing purposes. Federal law distinctions in the Affordable Care Act regarding group size apply for all other purposes unless otherwise specified. As discussed below, where State rate filings laws do not contain definitions of small and large group markets, we propose to employ the definitions in the Public Health Service Act, with the caveat that the number used for a cut-off between small and large groups would remain at 50 employees, as is currently the case in all States, even though States have the option of using 100 employees prior to 2016, and a 100 employee cut-off would be used after that date.

Rate increases for health insurance coverage for “excepted benefits,” as described in paragraph (1) of subsection (c) of section 2791 of the PHS Act, or in paragraphs (2), (3) or (4) of such subsection, if the benefits are provided under a separate policy, certificate of contract of insurance, would also be exempted from review under this proposed regulation. Excepted benefits, such as dental and vision, do not appear to be a principal focus of the Affordable Care Act, and the regulatory burden that would be imposed on the industry and HHS would not justify reviewing rate increases for these benefits.

All rate increases that meet or exceed the 10 percent threshold would be reviewed, by the relevant State, or by HHS in the smaller number of cases where States do not yet have an effective process in place. The proposed regulation would use the definition of States set forth in section 2791(d)(14) of the PHS Act, which defines States to include each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands. Consistent with the statutory

requirement in section 2794 that the rate review process be established “in conjunction with the States,” the proposed regulation provides that HHS would adopt a State’s determination of whether a rate increase is unreasonable if the State has an effective rate review program for rates filed in a particular market. This element of the proposed regulation preserves the primary role States have today in reviewing rates. So long as a State can conduct an effective review of proposed rate increases that meet or exceed the applicable threshold, State determinations will be adopted by HHS.

HHS expects that a significant majority of States would currently meet the standards for having an effective review process in one or both of the individual or small group markets, and we anticipate the remainder would likely establish an effective rate review process as they obtain needed statutory authority or implement new or enhanced review procedures. More than 10 States indicated in their applications for rate review grants they would be seeking additional legislative authority to enhance their existing processes.

HHS would evaluate whether a State has an effective rate review program based on four main factors, all of which currently represent the best practices among the many States which conduct review today. The first factor is whether the State receives from health insurance issuers’ data and documentation sufficient to determine whether a rate increase is unreasonable. As noted above, many States have these provisions today. The second factor is whether the State effectively reviews the data and documentation submitted by health insurance issuers in support of a rate increase. The third factor is whether the State review examines the reasonableness of the assumptions used by the issuer in developing its rate proposal and the historic data underlying those assumptions. The proposed regulation also describes the areas of analysis that a State’s review would be required to include in order for it to be deemed effective. The fourth factor is whether the State applies a standard set forth in statute or regulation when making the determination of whether a rate increase is unreasonable. This proposed regulation does not establish a standard for unreasonableness that a State must use or apply; nor does it require a numerical standard to be applied under State law to determine whether a rate increase is unreasonable. Rather, a State regulator would apply the applicable standards that exist under State law. Finally, we are soliciting public

comment on whether the public’s ability to comment on unreasonable rate increases during the review process should be considered as one criterion for an effective rate review program.

As noted above, section 2794 does not provide a definition of “unreasonable” rate increases. The proposed regulation provides that States would apply the standards set forth in State law or regulation when determining whether a rate increase is unreasonable. As mentioned above, many States’ laws provide that rates may not be approved, or may not remain in effect, if they are excessive or unreasonable in relation to the benefits provided or fail to satisfy other statutory standards. Specifically, our review of States’ laws indicates that 43 of the 50 States currently have some rate review process in either the individual or small group markets, or both. 16 States and the District of Columbia explicitly prohibit insurance rates from being excessive, inadequate, or unfairly discriminatory. In addition, 13 States prohibit rates from being both unreasonable in relation to the benefits provided and excessive, inadequate, or unfairly discriminatory. Finally, an additional 14 States prohibit rates from being unreasonable in relation to the benefits provided. For the remaining 8 States, we did not identify any explicit statutory standards that address the unreasonableness of rates; however, these States may use other legal tools available to regulate unreasonable rates. In addition, based on the rate review grant applications, some Territories either have a rate review process in place today, or expect to implement a process in the future.

When a State with an effective rate review program determines whether a rate increase violates the standards set forth in State law and therefore whether the increase is unreasonable, HHS would adopt that determination and would not conduct an independent review of the State’s determination. Given this proposed regulation, and the rate review grants made available to States under Section 2794 of the PHS Act, it is likely that, as States gain rate review authority and improve their rate review programs, the number of States in which HHS would be conducting reviews would diminish over time.

For rate increases filed in markets for which a State does not have an effective rate review process, HHS would conduct a review of the proposed rate increases to determine whether they are unreasonable until such time as the State implements an effective review process in that market. This proposed regulation provides that where HHS conducts rate reviews, the standard for

unreasonable would be whether the rate increase is “excessive,” “unjustified,” or “unfairly discriminatory.” The proposed regulation lists the factors that HHS would consider when determining if a rate increase is excessive, unjustified or unfairly discriminatory, and therefore, unreasonable.

Consistent with the statutory requirement that a “justification” be filed before an unreasonable rate may be implemented, the regulation also proposes to require that for rate increases that are subject to review (because they meet or exceed the 10 percent review threshold), a preliminary justification would have to be submitted to the applicable State in which the increase is proposed to be implemented, as long as a State accepts such submissions, and to HHS. The regulation sets out the proposed contents of the preliminary justification. The preliminary justification would be divided into three parts, each part having a different purpose. The proposed regulation would require health insurance issuers to complete parts one and two of the preliminary justification, regardless of whether a State or HHS is reviewing the rate increase. The information that would be contained in parts one and two of the preliminary justification is intended to provide consumers with a description of the rate increase and the factors contributing to the increase, including both a descriptive and a quantitative analysis.

The information required to be provided in the preliminary justification supplements, and does not conflict with, State laws specifying what issuers must file with the State when they propose to increase rates. Those laws continue to govern what the issuer must file with the State, and would be unaffected by this proposed regulation and the requirement that the preliminary justification must be filed with HHS.

When HHS is reviewing a rate increase, issuers would be required to submit the additional data required under part three of the preliminary justification in order to allow HHS to conduct a comprehensive actuarial review of the increase. The specific data reporting requirements in part three of the preliminary justification are modeled on the actuarial memorandum guidelines included in NAIC Model Regulation 134–1. In the event the level of detail provided by a health insurance issuer does not provide a sufficient basis for HHS to review a rate increase, HHS would request from the health insurance issuer the additional information necessary to complete its review.

Parts one and two of the preliminary justification would promptly be posted to the HHS Web site so that insurance consumers are on notice of proposed increases and have basic information about the factors the issuer asserts are causing the increase. HHS will also post on its Web site before any information contained in part three of the preliminary justification that has not been designated as “confidential” as defined in HHS’s Freedom of Information Act regulations, 45 CFR § 5.65. HHS will make a determination as to whether to post information designated as “confidential” under the standards and procedure set forth in those regulations, and will post that information only after making a determination that it is subject to disclosure as provided by those regulations.

If HHS reviews a rate increase and determines it to be unreasonable, HHS would provide its final determination to the health insurance issuer. If the issuer chooses not to implement the unreasonable rate increase, or to implement a lower increase than it had proposed and such lower increase is below the applicable subject to review threshold, the issuer would be required to provide a final notification to this effect to HHS. If the issuer chooses to implement a lower increase but the lower increase is above the applicable subject to review threshold, the lower increase would be subject to review and the issuer would be required to submit a new preliminary justification. If the issuer implements an unreasonable rate increase, it would have to provide to HHS a final justification in response to HHS’s determination of unreasonableness. HHS would post its final determination and the issuer’s final notification or final justification on its Web site. If the issuer chooses to implement the rate increase, it would be required to post its preliminary justification, HHS’s determination and its final justification on its Web site.

One of the elements of an effective rate review program, discussed more fully below, is that the State’s review would include an analysis of certain specific factors set forth in this proposed regulation and which are based on the common practices that States employ today. In addition, the State would provide to the issuer and to HHS its determination of whether a rate increase is unreasonable, along with an explanation of how its analysis of the factors set forth in the proposed regulation caused it to arrive at that determination. HHS would adopt determinations made by States with effective rate review programs. When

HHS has adopted a State’s determination as to whether a rate increase is unreasonable, HHS would post the State’s final determination on its Web site, together with the issuer’s final justification in the event that the issuer chose to implement a rate increase that was determined to be unreasonable by the State.

B. Definitions (§ 154.102)

The proposed regulation provides the following key definitions that would apply to the rate review process used by HHS, and to its determination regarding whether a rate increase is unreasonable. The definitions are discussed here because they are unique to this regulation or may be of particular interest to enrollees, health insurance issuers, consumers, regulators, and others. Defined terms that conform to definitions commonly used in the health insurance industry, such as “insurance,” or that have already been defined in Federal law, are not discussed here.

1. Individual Market and Small Group Market

As discussed above, in order to ensure that the rate review process outlined in the proposed regulation is consistent with the process used by States in performing rate reviews, and in order to avoid any disruption to the current State rate filing and review practices, the definitions of “individual market” and “small group market” would be defined as they are under the applicable State’s rate filing laws, if such laws include such definitions. For example, several States define a small group to include 2 to 25 employees for rating purposes, and the small group rating requirements in these States do not apply to groups with 26 or more employees. Further, certain States consider association plans to be large employers for rating purposes. In such circumstances, and only for this purpose, HHS would defer to applicable State law when determining whether a rate increase in that State relates to the small group market. For all other purposes the definitions set forth in the PHS Act govern as applicable.

In addition, for purposes of rate review under this regulation only, if the State rate filing law does not include a definition of small or large group, the definition under the PHS Act would be used, except that a small group would be defined to include 1 to 50 employees. Currently, under the Affordable Care Act definitions, States have the option until 2016 of using 50 or 100 as the cutoff for a small group, with 100 applying after that date, and all States have elected the 50 option. Thus, if

there are no definitions of small and large group in a State's rate filing law, this proposed regulation would define "small group" to include 1 to 50 employees.

2. Unreasonable Rate Increase

The proposed regulation defines a rate increase as "unreasonable" if it is "unjustified," "excessive," or "unfairly discriminatory," as these terms are more fully described in § 154.205, but this proposed definition would apply only to rate increases that are reviewed by HHS, and would not create a Federal standard for States to use when determining whether a rate increase is unreasonable. These terms are described consistently with the standards that are most commonly used by States to identify rate increases that are not in compliance with State law.

Since HHS would be adopting the determinations of States with an effective rate review program, the proposed regulation includes in the definition of "unreasonable rate increase," those rate increases that have been determined by a State to be excessive, unjustified, unfairly discriminatory or otherwise unreasonable under applicable State law. Accordingly, a State with an effective review program would be permitted to use any applicable standards set forth in statute or regulation for determining whether a rate increase that is subject to review is unreasonable. This serves to preserve and recognize existing State laws relating to unreasonable rates. HHS recognizes that factors other than those addressed in the proposed regulation may be viewed as potentially impacting the reasonableness of a rate, including the structure and competitiveness of the market, and we are therefore soliciting public comment to identify these factors and whether they should be considered in determining whether a rate increase is unreasonable.

C. Applicability (§ 154.103)

The requirements of this proposed regulation would generally be applicable to all health insurance issuers offering small group or individual health insurance coverage in a State.

Section 2794 of the PHS Act does not apply to grandfathered health plan coverage (*See* 45 CFR 147.140 (75 FR 34538, June 17, 2010, as amended by 75 FR 70114, November 17, 2010)), so these proposed regulations similarly would not apply to such coverage.

In addition, insurance coverage that meets the "excepted benefits" definition set forth in section 2791(c) of the PHS

Act and 45 CFR 144.103 would not be subject to these proposed regulations. While "excepted benefits" are not explicitly exempt from section 2794 of the PHS Act, they are exempt from other provisions of the PHS Act, as added by the Affordable Care Act. "Excepted benefits" do not appear to be the focus of the rate review provisions of the Affordable Care Act. Therefore, the proposed regulation would exempt "excepted benefits," to allow for the consistent administration of the PHS Act with respect to these defined benefits.

While HHS recognizes that the rate review provisions of section 2794 of the PHS Act do not specify to which particular segments of the insurance market the rate review provisions apply, and contain no specific exclusion for the large group market, HHS proposes that these provisions should only apply to the small group and individual market at this time. The significant majority of States focus their efforts on review of rates within the small group and individual markets. Purchasers in the large group market are viewed as more sophisticated purchasers, who may have greater leverage and therefore better ability to avoid the imposition of unreasonable rate increases, also mitigating the need for more active regulation. Many States have limited authority over the large group market, so under the framework set out in this regulation, few States could satisfy the standards for an effective review process in the large group market. Taking these factors into consideration, as noted above, these proposed regulations would not apply to the large group market. HHS may, however, revise these regulations at a future date to cover such plans, and solicits specific comments on whether, in the future, if rate increases in the large group market were subject to a review process under Section 2794, that process should be different than the one provided for in this regulation for the small and individual group markets.

Although section 2794 of the PHS Act directs that implementation of the annual rate review process begin with the 2010 plan year, the rate review process established in the proposed regulation would begin implementation with rate increases filed in a State on or after July 1, 2011, or effective on or after July 1, 2011 in a State that does not require rate increases to be filed, due to several factors. At the time that the Affordable Care Act amendments to the PHS Act first became effective, on March 23, 2010, many health insurance issuers had already implemented rate increases for the 2010 plan or policy year, and many more had taken

necessary steps to implement increases in the immediate months that followed. Since that time, in fulfilling the statute's directive that an effective rate review program be developed in conjunction with the States, the National Association of Insurance Commissioners (NAIC) has been working to develop appropriate reporting and disclosure mechanisms, and HHS has provided input into this development process. HHS also deemed it appropriate to solicit public comments prior to the promulgation of this proposed regulation, through the Request for Comments published on April 14, 2010. Finally, this regulation is being issued in proposed form, with opportunity for further comments which specifically address this proposed regulation. Therefore, as noted, the rate review process outlined in this proposed regulation would begin with rate increases filed in a State on or after July 1, 2011 or effective on or after July 1, 2011 in a State that does not require rate increases to be filed.

D. Rate Increases Subject To Review (§ 154.200)

1. Applicable Threshold for Rate Increases Subject To Review

As explained previously, while section 2794 of the PHS Act directs the Secretary to establish a process for the annual review of unreasonable increases in "premiums," HHS has interpreted this as referring to the underlying "rates" that are used to develop the premiums. This is consistent with how these terms are most commonly used by State regulators and the insurance industry. Often, the rate review process performed by States is one that reviews changes to the rating structure for a plan or policy, as opposed to premium increases within the plan or policy that are derived from the underlying rating structure. Therefore a "rate increase" alters the underlying rate structure of a policy form, while a "premium increase" can occur even without any increase (or change) to the underlying rate structure. For example, for policies that are age-rated, as the duration of the policy advances, premium changes that correlate with age bands are not "rate increases," since they do not change the underlying rate structure. For these reasons, the term "rate" is used instead of the statutory term "premium" throughout the text of the proposed regulation.

Since it is not possible under the provisions of this proposed regulation to know before conducting a review of a proposed rate increase whether it is "unreasonable," the process that would

be established must provide for the review of a range of proposed rate increases, some of which ultimately would be determined to be unreasonable, while others would not. This proposed regulation therefore provides that for health insurance coverage offered in the individual or small group market all proposed rate increases above the defined threshold would be "subject to review." In establishing a threshold for rate increases subject to review, the Secretary has balanced the need to set a standard that would effectively capture unreasonable increases, while avoiding unnecessary filing burdens for health insurance issuers with regard to increases that are likely to be reasonable.

The review of a rate increase subject to review, and the determination of whether the rate increase is unreasonable, must take into account the unique experience of a health insurance product and cannot be subject to a simple, fixed value. Therefore, under the proposed rule, a rate increase that is subject to review would not be per se unreasonable. For 2011, the threshold for whether a rate increase is subject to review is a rate increase of 10 percent or more. This applies not only to a single rate increase, but also to multiple rate increases of less than 10 percent that, when added to one or more previous increases within the preceding 12 month period, total 10 percent or more.

In establishing the 10 percent threshold, as noted earlier, HHS reviewed available data and literature on insurance rate increases in States and general trends in health care costs. HHS reviewed each State's applicable Web site, and determined that the information related to rate trends posted on these Web sites is limited. A small number of States make available data on rate increases in different insurance market segments in that State. Our review of this data suggests that the majority of increases in the individual market exceeded 10 percent each year for the past 3 years. Trends are slightly lower in the small group market, but over 40 percent of increases still exceeded 10 percent. In fact, in the States examined, rate increases in the individual market and small group market typically exceeded 15 percent. These yearly increases significantly exceed some national measures of medical cost inflation, such as the medical component of the Consumer Price Index, whose inflation has typically ranged from 3.7 percent to 4.4 percent. The Centers for Medicare and Medicaid Services' National Health

Expenditures (NHE) data is another measure of health care cost trends based on overall national health care spending. The five most recent years of available NHE data suggest that overall health care expenditures have increased at an annual rate between 4.4 percent to 6.9 percent. Commenters point out that the factors which account for the NHE or the medical component of the CPI are different than the various components that account for increases in insurance rates. For example, the medical component of CPI does not take into account utilization of health care services, or the risk profiles of specific populations but is instead based on prices for certain services provided to the general population. Health insurance rates are affected, not only by the prices charged by the providers of health care services, but also by changes in the rate at which those services are accessed and the characteristics of the group covered by the insurance. Another national index, the Standard & Poor's Healthcare Economic Commercial Index, also measures insurance rate trends. The S & P Index measures trends in provider claims costs, which encompasses both unit cost and utilization changes; the trend in that index from September 2009 to September 2010 was 8.5 percent.

In establishing a 10 percent threshold for determining which rates are subject to review, HHS has balanced the wide range of available data on rate and medical trend increases. If, for example, the NHE or medical component of the CPI represented an accurate measure of insurance rate trends, then a threshold for review could be established consistent with those indices under the theory that rate increases in line with those trends were reasonable because they tracked medical cost trends generally, and increases that exceed those measures are more likely to be unreasonable. However, since neither of those particular measures captures the many factors that affect insurance rates, using those measures as a threshold for reviewing rates under section 2794 would be over-inclusive. Under that approach, rather than capturing potentially unreasonable or excessive rate increases, almost all rate increases would be subject to review. Such a result would not be consistent with the intent of section 2794. For these reasons, a 10 percent threshold is a reasonable accommodation between the observed, but limited data available regarding trends in rate increases in the States, and the available but not precisely comparable data on general trends in health care costs and

spending, and recognizes that other factors may justify a larger rate increase.

As noted earlier, the Secretary would seek to establish a State-specific threshold for each future calendar year no later than September 15th of the preceding calendar year, beginning in 2011, provided applicable State-specific trend data is available. If a State-specific threshold is not established by the Secretary for an applicable calendar year, the 10 percent threshold would continue to apply.

A State-specific threshold, to the extent it can be developed, would be based on the same kind of analysis used in establishing the proposed 10 percent threshold, but would account for State-specific variations in rate increases based on the cost of health care, utilization patterns, and other factors affecting health insurance rates in a State. HHS would use trend data and other information made available to HHS from States receiving premium review grants and through the reporting and notification requirements of this proposed regulation to develop State-specific thresholds, when possible.

In developing the 10 percent threshold, the Secretary considered the level of aggregation that should apply when determining whether a rate increase meets or exceeds the threshold, and the Secretary received numerous comments on this issue. Comments received from issuers, the American Academy of Actuaries, and industry groups proposed the use of a higher level of aggregation of multiple policy forms to improve statistical credibility. Typically, this aggregation occurs within a market segment. Consumer groups, on the other hand, generally favored lower levels of aggregation. Finally, various State regulators sent comments describing how individual State rate review laws affect the level of aggregation used in performing rate reviews.

In considering the broad range of perspectives represented by the comments on aggregation, the proposed regulation requires the consideration of rate increases at the "product" level when determining whether the increase is subject to review. Product would be defined under this proposed regulation as 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. Most States require issuers to submit each "product" as a separate form filing prior to marketing the "product" in the State. While each filed "product" may include variable options (such as different cost-sharing or deductible requirements), this definition,

consistent with State law, does not consider each variable option as a separate “product.” Any rate increase for a product that meets or exceeds the applicable threshold is subject to review. However, if an issuer has rate increases that meet or exceed the applicable threshold for multiple products, the issuer may submit a single, combined preliminary justification for those products combined, provided (i) the experience of all combined products has been aggregated to calculate the rate increases, and (ii) the rate increase is the same across all combined products.

2. Determining Whether a Rate Increase Meets or Exceeds the Threshold

A rate increase would meet or exceed the applicable threshold if the weighted average increase for all enrollees subject to the rate increase meets or exceeds the applicable threshold. In this case, the weighted average takes into account the number of enrollees affected by each particular rate increase and represents the given increase proportionately. Specifically, we assume that different subcategories of enrollees will experience varying rate increases. The weighted average is calculated as follows: For each subcategory of enrollees subject to the same rate increase, we multiply the number of enrollees by the respective rate increase. The products are then summed over all subcategories. The sum is then divided by the total number of enrollees to arrive at the weighted average rate increase.

A rate increase meets or exceeds the threshold either by itself, or when considered cumulatively with any previous rate increases implemented with respect to the product during the preceding 12-month period. Therefore, a single rate increase which by itself falls below the applicable threshold must be aggregated with rate increases implemented during the 12 month period preceding its effective date in order to determine whether it is subject to review. If a rate increase 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, the rate increase is subject to review, and such review shall include a review of the aggregate rate increases during the applicable 12-month period.

E. Review of Rate Increases Subject To Review by a State or by HHS (§ 154.210)

As noted above, under this proposed regulation, States would continue to have primary responsibility for the

review of rate increases. HHS would only review rates when a State has not yet established a process, including adequate legal authority, to do so. While not every State is currently equipped to conduct an effective review of insurance rates, the significant majority of States have a review process for some or all of the individual or small group markets, and many are planning to expand their authority to review rates using the grants provided in the Affordable Care Act detailed below. We fully expect that the vast majority of States will be able to conduct effective reviews in the future, should they choose to.

A Kaiser Family Foundation survey designed to explore what rate review authority States have and how they exercise it, identifies various reasons that explain why there is wide variation in the review of rate increases by States.² Some States have no legislative authority to approve or disapprove rates, while others have the authority to approve rates prior to implementation, or disapprove rates before or after implementation. Among States with robust legislative authority, a thorough rate review is contingent on State resources, staffing, and statutory timelines. The effectiveness of a State rate review program depends on State law as well as insurance department resources and practices, and will be determined, for purposes of this regulation, based on the State’s ability to meet the criteria set forth in § 154.301.

Section 2794(c) of the PHS Act established a program to award “premium review grants.” Section 2794(c) makes available a total of \$250 million through 2014 for the provision of grants to States to support their efforts to enhance review of premium increases. These grants are available to States with the goal of improving existing rate review programs, developing rate review programs in States where none exist, and improving the transparency of the rate review process for the public. On August 16, 2010 HHS announced the first cycle of grant awards totaling the amount of \$46 million to build upon States’ current processes for reviewing, and to the extent permitted by State law, approving health insurance premium increases. Forty-five States and the District of Columbia applied for grants, and each was awarded \$1 million in grant funds.

In applying for the first phase of these grants in 2010, some States indicated a

² Kaiser Family Foundation, “Rate Review: Spotlight on State Efforts to Make Health Insurance More Affordable,” December 2010, available at <http://www.kff.org/healthreform/upload/8122.pdf>.

need for additional resources to make the State’s rate review program more effective. Many States indicated they lacked funding to hire actuaries and to secure other resources essential to a meaningful rate review program. Therefore, the rate review process under this proposed regulation, in conjunction with the rate review grant program, would enhance the quality and quantity of review of rate increases that States are able to conduct, building on their existing efforts and processes.

By requiring the Secretary to develop a rate review process in conjunction with the States, Congress also recognized that many States have significant experience reviewing rate increases and understand the local market forces driving health insurance rate increases. Therefore, HHS is proposing a rate review process that leverages State experience and expertise.

Section 154.210 of the proposed regulation sets forth the factors that would determine whether HHS would review rate increases that are subject to review or whether HHS would adopt the determination made by a State regarding whether a rate increase is an unreasonable rate increase. To the extent that a State has an effective rate review program in a given market, as evaluated by HHS using the criteria set forth more fully below, HHS would adopt that State’s determinations regarding rate increases subject to the State’s review in a given market. Accordingly, upon receipt of the State’s final determination and explanation for its determination, HHS would adopt the determination of a State that has an effective rate review program regarding whether a rate increase is unreasonable under applicable State law. If a State does not have an effective rate review program in place for the individual or small group markets within the State, only then would HHS review rate increases and make its own determinations of whether the rate increases are unreasonable.

F. Effective Rate Review Program (§ 154.301)

1. General Criteria for an Effective Rate Review Program

This regulation sets out specific criteria, set forth in § 154.301(a), for evaluating whether a State has an effective rate review program in the individual and small group markets. Specifically defining these criteria provides transparency to the rate review process as these criteria are readily available to the States, health insurance issuers, and consumers. These criteria

were developed solely for the purpose of establishing the standards that HHS would use to evaluate, in consultation with the States, whether a State's rate review process is effective, or whether HHS would conduct rate reviews and make a determination as to whether a rate increase is unreasonable. Since a State may be in the process of improving its rate review program, and may be using grant funds and other resources for this purpose, HHS would make its determination based on the State's existing rate review program, including any recent changes made that would satisfy the criteria for an effective rate review program set forth in § 154.301(a).

Under proposed § 154.301(a)(1), we set forth four criteria for an effective rate review program. These criteria are drawn from common practices that States use today for effective reviews. Underlying these proposed criteria is the principle that the purpose of an effective rate review program is to affirmatively determine, based on substantial evidence on the record as a whole, whether a rate increase is an unreasonable rate increase. The proposed regulation specifies that in order for a State's rate review program to be considered effective, the State needs to have the legal authority to obtain data and documentation that is sufficient to conduct an effective examination. The State would also be required to effectively review data and documentation submitted in support of rate increases. An effective rate review program would have to include an examination of both (i) the reasonableness of the assumptions used by the health insurance issuer in developing the rate proposal and the validity of historical data underlying such assumptions; and (ii) the issuer's data related to past projections and actuarial experience. As is the case for those States conducting effective review today, this examination of assumptions and past projections would be required to include analyses of at least the following twelve areas that typically impact rates:

- Medical trend changes by major service categories;
- Utilization changes by major service categories;
- Cost-sharing changes by major service categories;
- Benefit changes;
- Changes in enrollee risk profile;
- Impact of over- or under-estimate of medical trend in previous years on the current rate;
- Reserve needs;

- Administrative costs related to programs that improve health care quality;
- Other administrative costs;
- Applicable taxes, licensing or regulatory fees;
- Medical loss ratio; and
- The health insurance issuer's risk-based capital status relative to national standards.

Finally, the State's determination of whether a rate increase is unreasonable would be made under a standard that is set forth in State statute or regulation. As noted above, 43 States have some standard under State law that would apply to the review of unreasonable rates. This proposed regulation does not establish a standard that States must apply.

2. HHS's Determination Whether a State Has an Effective Rate Review Program

We fully expect that the vast majority of States will be able to conduct effective reviews in the future. HHS expects that the majority of States would currently meet the standards for having an effective review process, and many more would become effective review States as they obtain needed statutory authority or implement new or enhanced rate review processes. So long as a State can conduct an effective review of proposed rate increases that meet or exceed the applicable threshold, States will not be "second-guessed" by HHS. Working with the States, HHS would evaluate whether a State's rate review program meets the requirements of an effective rate review program set forth in § 154.301(a) based on documentation and information received from the State through the grant process, through review of applicable State law, and through any other information otherwise available to HHS. Unless a State were no longer conducting reviews in accordance with the criteria set forth in proposed § 154.301(a), HHS would not conduct reviews for rate filings in that State. If after an initial determination has been made by HHS that a State's rate review program is not effective, HHS would subsequently be able to determine that later improvements made by the State to its rate review program have made it an effective rate review program. HHS would post on its Web site a list of those States having effective rate review programs, and would update this list from time to time, as appropriate.

G. Unreasonable Rate Increases (§ 154.205)

Under the proposed regulation, when HHS reviews a rate increase, HHS would 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. The factors that make a rate increase excessive, unjustified or unfairly discriminatory are described in 154.205. HHS would consider all of these factors in determining whether a rate increase is unreasonable. The factors used to determine whether a rate increase is unreasonable would only apply to rate increases that are reviewed by HHS. Each State would apply its own State standards when reviewing a rate increase to determine whether it is unreasonable.

HHS recognizes that factors other than those addressed in the proposed regulation may be viewed as potentially impacting the reasonableness of a rate, including the structure and competitiveness of the market, and we are therefore soliciting public comment to identify these factors and whether they should be considered in determining whether a rate increase is unreasonable.

1. Excessive Rate Increase

An excessive rate increase is a rate increase that is subject to review and that causes the premium charged for the health insurance coverage to be unreasonably high in relation to the benefits provided. HHS recognizes that identifying objective measures that would be considered in determining whether a rate increase is excessive would be helpful to both issuers and the public. The proposed regulation therefore would describe several objective measures that HHS would consider in determining whether a rate increase causes the premiums charged to be unreasonably high in relation to the benefits provided.

First, HHS would consider whether the rate increase results in a projected future loss ratio below the Federal medical loss ratio (MLR) standard determined under section 2718 of the PHS Act for the applicable market to which the rate increase applies. HHS recognizes that under the regulations implementing the MLR standards, 75 FR 74864 (December 1, 2010), generally issuers must meet the relevant MLR standard in each State by aggregating all of their business in a particular market segment. The consequence of this approach is that an issuer may meet the MLR standard in the aggregate even if a particular insurance product does not meet the relevant standard so long as the combination of all products in the market by the issuer meets the Federal standard. Therefore, while the MLR is not a determinative factor, MLR

standards serve as a benchmark against which the reasonableness of rates are measured in the industry and the approach that would be adopted under this proposed rule is consistent with the approach taken in States that have had MLR standards under State law. Under this proposed approach, if an issuer proposed an increase of 10 percent or more (an increase that would be subject to review) for one or more individual market products, and the projected MLR for the product or products was below 80 percent, the increase nonetheless would not necessarily be considered excessive if the issuer could demonstrate that the aggregate MLR for all products in the individual market in that State would be at or above 80 percent.

Notably, the Federal MLR standard under the Public Health Service Act also takes into account certain adjustments such as credibility adjustments to account for newer and smaller plans and other special cases. HHS would consider the issuer's adjusted Federal medical loss ratio in the applicable market to which the rate increase applies when determining whether an increase is excessive.

Second, in determining whether a rate increase is excessive, HHS would consider whether one or more of the assumptions on which the rate increase is based are not supported by substantial evidence. Finally, HHS would consider whether the choice of assumptions or combination of assumptions on which the rate increase is based is unreasonable.

2. Unjustified Rate Increase

Included in this proposed regulation are provisions that would require health insurance issuers to provide a defined set of data and documentation to HHS, to permit HHS to determine whether a rate increase is "unjustified." A proposed rate increase that is subject to review would be "unjustified" if the health insurance issuer provides data or documentation to HHS 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. Therefore, issuers would be required to provide data and documentation that is sufficient for HHS to conduct a meaningful review of a rate increase.

3. Unfairly Discriminatory Rate Increase

Under the proposed regulation, an unfairly discriminatory rate increase is one that results in premium differences for a particular product between insureds within similar risk categories

that are not permissible under applicable State law or, if no State law applies, do not reasonably correspond to differences in expected costs. In this context, a risk category is a classification of a group of insureds who share a common set of descriptive characteristics, such as age or geographic location, and are covered under a single product. Health insurance issuers charge different premiums to insureds that fall within different risk categories.

More than 25 States prohibit health insurance rates from being unfairly discriminatory. Therefore, the proposed regulation would define an unreasonable rate increase to include an unfairly discriminatory rate increase. In order to develop the factors that would make a rate increase an unfairly discriminatory rate increase, HHS reviewed factors applied by States to determine whether a rate increase is unfairly discriminatory.

In our review, we concluded that States determine whether a rate increase is unfairly discriminatory based on the specific rating requirements under applicable State law. For example, if a State's rating law prohibits price discrimination within a rating cell (a subcategory of enrollees with particular characteristics in common, such as age, geographical location or tobacco status), a rate increase in that State would be unfairly discriminatory if the increase varied between individuals with the same characteristics within a given rating cell. If a State's rating law requires community rating (the practice of charging a common, unadjusted premium to all members of a diverse pool who may have widely varied health spending for the year) or prohibits the use of a specific rating factor such as geographical location, age or tobacco status, a rate increase in that State would be unfairly discriminatory if the increase was calculated based on a prohibited rating factor or does not account for pooled experience under the State's community rating requirements.

Therefore, under the proposed regulation, an unfairly discriminatory rate increase would be one that results in premium differences not permissible under applicable State law between insureds within similar risk categories or, if no State law applies, do not reasonably correspond to differences in expected costs. This approach would give deference to applicable State rating laws, and give HHS the ability to determine that a rate increase is unfairly discriminatory in the absence of applicable State law.

H. Issuer Disclosure Required Under Part 154

1. Preliminary Justification

The proposed regulation would require health insurance issuers to submit a preliminary justification for all rate increases subject to review, regardless of whether a State or HHS is reviewing the rate increase. The format of the preliminary justification would be provided in guidance. In order to minimize the burden on health insurance issuers to complete the preliminary justification, HHS is developing a web-based program that would allow health insurance issuers to complete and submit the preliminary justification electronically. The information contained in parts one and two of the preliminary justification would be intended to provide consumers with a thorough description of the rate increase, including both a narrative descriptive and a quantitative analysis. Further, parts one and two would provide consumers with the context necessary to interpret a State's or HHS's determination as to whether a rate increase is unreasonable. HHS is sensitive to placing an increased reporting burden on health insurance issuers, but believes that the majority of issuers would have the information required in parts one and two of the preliminary justification readily available, since this is the type of information generally used by issuers to calculate their rates.

In developing the requirements for parts one and two of the proposed preliminary justification, HHS has reviewed and incorporated elements from a comparable form developed by the NAIC over a period of several months. For example, State regulators expressed the view that consumers need more than just quantitative information, such as cost and utilization trend factors, to interpret a rate increase. Regulators recommended that issuers be required to provide a narrative explanation of applicable rate increases that supports and explains the key quantitative information associated with the increase. The narrative also should describe, in a straightforward fashion, the rationale for the rate increase. The preliminary justification therefore would require issuers to provide high level quantitative data associated with a rate increase along with a written narrative explaining the increase.

If HHS is responsible for reviewing a rate increase, HHS would conduct a comprehensive actuarial review of the increase. In this case, issuers would be required to submit additional information in part three of the

preliminary justification. As noted above, the specific proposed data reporting requirements in part three of the preliminary justification are modeled on the actuarial memorandum guidelines included in NAIC Model Regulation 134-1. These guidelines set forth reasonable standards for reporting and justifying rate increases, and this type of data comprises a typical rate filing in those States that require rates to be filed. Therefore, HHS anticipates that these data would be readily available to most issuers. Shortly following the release of this proposed rule, HHS will release via the **Federal Register** a draft version of the preliminary justification for public comment. The draft preliminary justification will provide the formatting and reporting instructions for each of the reporting categories listed in the regulation.

Part one of the preliminary justification, titled "rate increase summary," would require issuers to submit the following data underlying the rate increase:

- (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.

Under part two of the preliminary justification, titled "written description justifying the rate increase," a health insurance issuer would be required to provide a written description of the rate increase, including: (1) An explanation of the rating methodology (that is, the method used to apply various rating factors, such as cost trends or benefit design, to the development of an insurance rate, as well as the formulae employed to apply those factors); (2) an 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 (3) a brief description of the overall experience of the policy, including historical and projected expenses and loss ratios.

Again, a health insurance issuer would be required to complete and submit sections one and two of the preliminary justification for all rate increases subject to review, regardless of whether HHS or a State is reviewing the rate increase. Issuers would be required to complete part three titled, "rate filing documentation," only in the event HHS is reviewing the rate increase. The rate filing documentation supports parts one and two of the preliminary justification, and the proposed regulation lists the following broad reporting data categories that would be required under part three, consistent with NAIC model requirements:

- (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 result under paragraph (e)(7) is less than the standard under paragraph (e)(9), a justification for this outcome.

When health insurance issuers provide rate filing documentation for each category in part three of the preliminary justification, they would have to be sufficient to permit HHS to conduct a thorough actuarial review of the rate increase. However, HHS would accept a State rate filing in lieu of the information required under part three, provided the rate filing includes the information required under such part. In the event a health insurance issuer does not provide sufficiently detailed information for HHS to review a rate increase and determine whether it is unreasonable, HHS would request from the health insurance issuer the information necessary to complete its review. HHS proposes to provide further details on the format by which the specific data elements would be

required to be submitted by this proposed regulation.

2. Submission of Final Justification or Final Notification

When a State with an effective rate review program receives notice of a rate increase subject to review, it would determine whether the increase is an unreasonable rate increase. The State would provide its findings and conclusions to HHS. In the situations when HHS reviews a rate increase, HHS would prepare a final determination and brief explanation of its analysis. If HHS determines that a rate increase is not unreasonable, or adopts a determination by a State that a rate increase is not unreasonable, the health insurance issuer would not be obligated to submit any additional information to HHS. If HHS determines that a rate increase is unreasonable, HHS would provide the final determination and explanation to the health insurance issuer. If HHS adopts a determination by a State that a rate increase is unreasonable, and the health insurance issuer is legally permitted to implement the unreasonable rate increase under applicable State law, HHS would provide the State's final determination and explanation to the issuer.

If the health insurance issuer intends to implement an unreasonable rate increase, the issuer would be required to submit a final justification to HHS. The justification would be a brief response to HHS's or the applicable State's final determination. If the issuer chooses not to implement the unreasonable rate increase, or chooses to implement a lower rate increase, it would be required to notify HHS to that effect. If the issuer implements a lower rate increase that does not meet or exceed the applicable threshold, the lower increase would not be subject to the proposed regulation. However if the lower rate increase does meet or exceed the applicable threshold, the increase would be subject to the proposed regulation and the issuer would be required to submit to HHS a new preliminary justification for the increase. The issuer would submit the final justification or final notification by the later of 10 days after (i) the implementation of such increase or (ii) the health insurance issuer's receipt of HHS's final determination that a rate increase is an unreasonable rate increase.

The purpose of the final justification would be to provide the health insurance issuer with an opportunity to respond to HHS's or the State's determination that its rate increase is unreasonable and to make the issuer's final justification available to health

insurance consumers. Since HHS would rely directly on information provided by the health insurance issuer when making the determination whether a rate increase is unreasonable, the health insurance issuer's final justification would have to be consistent with and based upon the information provided under the preliminary justification, and could not include new or different information that was not provided to HHS. Health insurance issuers would be required to provide their final justifications electronically to HHS through the web-based program developed by HHS.

As noted above, HHS's determination that a rate increase is unreasonable would not have any effect on the issuer's right to implement the rate increase, which is entirely a matter of State law. Similarly, HHS's review of rate increases would not delay the implementation of those increases; the timing of implementation is also a matter of State law.

3. Posting of Information on the HHS Web site

HHS proposes to promptly post on its Web site the information contained in parts one and two of the preliminary justification. Section 2794 requires the Secretary to ensure the public disclosure of information, including the justifications. The statute does not specify when this information must be posted, but HHS believes that Congress intended that the rate review process be transparent, and that this objective is served by giving consumers immediate access to basic information regarding the proposed increase that is under consideration by HHS or States and prior to the implementation of the rates that are subject to review. To avoid a misperception that these postings represent justifications for rate increases that are determined to be unreasonable, HHS will prominently place a disclaimer near the postings that: "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." We solicit public comment on the specific language HHS should use in its disclaimer. HHS considered disclosing this information later in the review process, such as when the review of the rate increase was completed, but determined that posting in this manner would reduce transparency and provide insufficient opportunity for consumer review of information related to these rate increases prior to implementation.

HHS does not consider the information contained in the preliminary justification to be confidential and believes that consumers would benefit from this information because it provides a basic description of the rationale underlying a rate increase. HHS also believes that the information under part three should be made public, but understands that issuers may consider certain of this information to be confidential. HHS would promptly post on its Web site any information provided in part three of the preliminary justification, as long as it has not been designated as "confidential" as defined in HHS's Freedom of Information Act regulations, 45 CFR 5.65. HHS will also make a determination as to whether to post information designated as "confidential" under the standards and procedure set forth in those regulations, and will post that information only after making a determination that it is subject to disclosure as provided by those regulations.

HHS would also post on its Web site the final determinations of both States and HHS that a rate increase is either unreasonable or not, as well as explanations for those determinations. In the event that either a State or HHS determines that a rate increase is an unreasonable rate increase and the health insurance issuer chooses to implement the rate increase, HHS would also post on its Web site the health insurance issuer's final justification.

4. Posting of Information on the Health Insurance Issuer's Web site

PHS Act section 2794 requires health insurance issuers to prominently post on their Web sites their justification for an unreasonable premium increase. Therefore, if HHS determines that a rate increase is unreasonable or adopts a determination by a State that a rate increase is unreasonable, and the health insurance issuer implements the rate increase, the issuer would be required to post on its Web site the information contained in the preliminary justification; HHS's final determination and explanation; and the issuer's final justification. In an attempt to minimize this posting burden, health insurance issuers would be able to download from HHS an electronic file containing the information required to be posted. Further, the health insurance issuer would have no obligation to post on its Web site any information regarding rate increases that are not determined to be unreasonable or that are not implemented. HHS proposes to issue

further guidance regarding the format of posting.

5. Timing of Submission of Preliminary Justification, Final Justification, Final Notice, and Issuer Posting

PHS Act section 2794 requires health insurance issuers to provide justifications for unreasonable rate increases prior to the implementation of such increases. As noted above, consistent with this requirement, HHS is proposing necessary timeframes for the completion of the preliminary justification by health insurance issuers. Specifically, if a State requires a health insurance issuer to file a proposed rate increase with the State prior to implementation of the rate, the issuer would be required to submit a completed preliminary justification when it submits the proposed rate increase to the State. This approach would allow HHS to receive the preliminary justification prior to implementation of a rate increase without creating an additional burden on health insurance issuers to include an extensive justification in their initial submission to the State.

If a State does not require a health insurance issuer to file a rate increase with the State, HHS anticipates that such State would not be found to have an effective rate review program. Therefore, HHS anticipates that it would be responsible for reviewing rate increases in those States. PHS Act section 2794 does not require issuers to submit rate filing data prior to implementation of a rate increase, and accordingly neither would this proposed regulation. Therefore, absent any State law to the contrary, issuers would have the option of completing the preliminary justification at the time of implementation or prior to that time. If HHS requires information in addition to the preliminary justification to complete its review, then the issuer would be required to provide this information within five business days following its receipt of the request.

In the event the issuer implements an unreasonable rate increase, the issuer would be required to submit a final justification to HHS and post the required information on its Web site within the later of 10 days after the implementation of the increase or 10 days after the issuer's receipt of the final determination by HHS that the rate is unreasonable. If an issuer determines that it will decline to implement or has withdrawn an increase determined by HHS to be unreasonable, or that it will implement a lower increase, it would be required to notify HHS of this decision within 10 days of its determination.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60 days 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. This proposed rule contains information collection requirements (ICRs) that are subject to review by OMB. A description of these provisions 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. 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 are soliciting public comment on each of these issues for the following sections of this proposed rule that contain information collection requirements (ICRs):

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 proposed regulation would establish a rate review program to ensure that all rate increases that meet or exceed an established threshold are reviewed by a State or HHS to determine whether the rate increases are unreasonable. Under the proposed regulation, if HHS determines that a State has an effective rate review program in a given market, using the criteria set forth in the proposed rule, HHS would adopt that State's determinations regarding whether rate increases in that market are unreasonable, provided that the State reports its final determinations to HHS, and explains the bases of its determinations. For all other States, HHS would 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 proposed regulation would therefore develop 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 HHS and the relevant State prior to its implementation. The proposed regulation would therefore establish 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 HHS to be unreasonable, and a notification requirement for unreasonable rate increases which the carrier will not implement.

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

This proposed rule describes the preliminary justification that each health insurance issuer would be required to submit to both HHS and States, if it is seeking to implement a rate increase that meets or exceeds the threshold described in § 154.200. The preliminary justification would include data supporting the potential rate increase as well as a written explanation of the rate increase. For those rates HHS would be reviewing, issuers' submissions would also include supplemental data and information that HHS would 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 one consists of a document (Excel spreadsheet) to be completed by issuers for all proposed rate increases that meet or exceed the threshold. Part two of the preliminary justification is a three- to five-page written narrative explaining the methodology used to derive the rate increase. Issuers would be required to submit to both HHS and the applicable State parts one and two prior to implementation of a rate increase, regardless of whether HHS is reviewing the rate increase or adopting the State's review. Issuers typically calculate these figures in order to develop a premium

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

Using 2010 data, HHS estimates the number of rate filings in 2010 that would have been subject to the proposed rule had it been in force to be between 3,635 and 4,015 in the individual and small group markets nationwide. HHS 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, HHS estimates that, in 2011, there would be 5,343 rate filings subject to the proposed rule. As discussed in the impact analysis section, HHS estimates that approximately 773 of these rate filings would require review under the proposed rule because they meet or exceed the established threshold.

At this time, HHS has not completed development of the draft forms for parts one, two, and three of the preliminary justification that issuers would have to submit should their rate increase be subject to review because it would meet or exceed the threshold. While these are new forms, we believe issuers are already collecting the data necessary to complete any form we develop. Because the forms are still under development, we cannot assign a complete burden estimate at this time. Once the forms are available, we will publish a notice in the **Federal Register** to solicit public comments on the forms and provide our burden estimates associated with this requirement.

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

Under the proposed rule, if HHS determines that a State has satisfied specific criteria for an effective rate review program under § 154.301, HHS 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 the Department and explains the bases 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 the Department to help States improve their rate review processes. In those cases where a State does not have an effective rate review program, HHS would make its own determinations regarding whether a rate increase that meets or exceeds the established threshold is unreasonable.

HHS would post on its Web site the information contained in each preliminary justification for each rate increase subject to review under § 154.200. For consumer clarity, HHS would also post on its Web site the final disposition of each rate increase reviewed by either HHS or a State. Therefore, either a State or HHS would make a final disposition for all rate increases reviewed under the proposed 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, HHS estimates that 773 rates would be reviewed under the proposed 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 HHS and posting dispositions on approximately two-thirds of these rates (or 515 filings) for at least one market. The RIA also estimates that reporting information from the State to Department will require approximately 20 minutes per filing. Thus the annual burden for this requirement is approximately 172 hours. HHS estimates that the additional burden of posting to the States would be negligible, since States currently post information about the disposition of rates. However, we welcome comments regarding the burden associated with the State posting burden requirements described in § 154.225.

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

The proposed rule would require health insurance issuers to submit to HHS and the relevant State a final justification for any unreasonable rate increase that would be implemented and to display this information on their Internet Web sites. If an issuer is legally permitted to implement an unreasonable rate increase and declines to implement the increase, the issuer

would provide notice to HHS that it will not implement the increase. As discussed in the impact analysis section, HHS estimates that 417 issuers will submit an estimated 371 to 1,396 rates for review and that it will take between 6 to 16 hours to complete the entire justification process. HHS estimates that 773 rates will meet or exceed the threshold and further assumes carriers will implement 100 percent of rates found unreasonable. We welcome comments regarding the burden associated with the State posting burden requirements described in § 154.230.

E. ICRs Regarding HHS’s Determinations of Effective Rate Review Programs (§ 154.301)

As discussed earlier in the preamble, HHS would 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 documentation and information received from the State through the grant process, through review of applicable State law, and through any other information otherwise available to HHS. The information collection for the “Grants to States for Health Insurance Premium Review” is approved under OMB Control number 0938–1092. Since HHS 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

45 CFR Section	Type of collection	Respondent	Number of respondents	Total annual responses	Hours per response	Total hours
§ 154.210	Reporting	States	25–35	515	0.33	172
§ 154.215 and § 154.220	Reporting	Issuers	417	773	TBD	TBD
§ 154.225	Disclosure	States	25–35	515	Negligible	0
§ 154.230	Reporting	Issuers	417	773	.5	386
§ 154.230	Disclosure	Issuers	417	773	.5	386

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and

Budget, Attention: OCIO Desk Officer, OCIO–9999–P, Fax: (202) 395–7245; or E-mail: OIRA_submission@omb.eop.gov.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. 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 notice of proposed rulemaking (NPRM) implements Section 2794 of the Public Health Service (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 NPRM as “rates”). This notice of proposed rulemaking outlines the methodology by which HHS would review proposed rate increases. HHS has proposed this regulation to implement 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. HHS 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.

B. Executive Order 12866

Executive Order 12866 (58 FR 51735) directs 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).

Section 3(f) of the Executive Order defines a “significant regulatory action” as an action that is likely to result in a proposed rule (1) having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. OMB has determined that this proposed rule is a “significant rule” under Executive Order 12866.

Accordingly, OMB has reviewed this proposed rule under the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with

economically significant effects (\$100 million or more in any 1 year); and a “significant” regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below, HHS has concluded that this proposed 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, HHS is not able to quantify the effect of this proposed rule on rates charged by issuers, and it is possible that the effect on rates will be large enough to cause the proposed rule to be considered a major rule. HHS invites comments on this issue.

Nevertheless, HHS opted to provide an assessment of the potential costs, benefits, and transfers associated with this proposed regulation.

1. Need for Regulatory Action

Consistent with the provisions in Section 2794 of the PHS Act, this NPRM when finalized would require health insurance issuers offering non-grandfathered coverage in the individual and small group markets to report information concerning rate increases to HHS and the applicable State if the proposed increase is 10 percent or higher. Section 2794(a) of the PHS Act (captioned “initial premium review process”) 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 proposed rule on

States will be small. In the States that do not currently conduct effective rate review, HHS will initially review those rate filings that meet or exceed the 10 percent threshold. HHS anticipates that those States will use the rate review grants described in the preamble to enhance their capacity for review. Moreover, HHS 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 proposed 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, HHS 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 HHS’ assessment of the benefits, costs, and transfers associated with this regulatory action. HHS limited the period covered by the regulatory impact analysis (RIA) to 2011–2013. 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, HHS estimates that this regulatory action would result in better information for consumers about their health insurance premiums and is likely to lower premiums. The proposed 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, HHS 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.

TABLE 1—ACCOUNTING TABLE—Continued

Costs:	Low estimate	Mid-range estimate	High estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized (\$millions/year)	7	12	19	2010	2011–2013
	6	11	18	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 proposed rule subjects proposed rate increases of ten percent or more to additional scrutiny in order to safeguard against this exercise of market power by insurers. The proposed 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

HHS has identified the primary sources of costs that would be associated with this proposed 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.

HHS estimates that issuers would incur approximately \$10 million to \$15 million in one-time administrative costs, and \$0.4 million to \$4.5 million in annual ongoing administrative costs related to complying with the requirements of this proposed rule from

2011 through 2013. In addition, States would incur very small additional costs for reporting the results of their reviews to the Federal government, and the Federal government would incur approximately \$0.6 million to \$4.8 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 Public Health Service 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 proposed rule apply to issuers that offer individual and small group coverage, and these issuers would 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 HHS' estimates of the number of entities and rate filings that would be affected by the requirements being proposed in this 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.³ 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, HHS estimates that there are 34.8 million enrollees in coverage that would be subject to the requirements being proposed in this 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 files, which excludes data for companies that are not required to file annual statements with NAIC).⁴

³ The analytic sample excludes companies that are regulated by HHS 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.

⁴ As noted above, issuers that are regulated by HHS 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.

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)	417	100.0	34,792	100.0
Number Offering Coverage In:				
Individual Market	311	74.6	10,603	30.5
Small Group Market ⁴	342	82.0	24,189	69.5

Notes:

¹ Issuers represents companies (e.g., 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 (e.g., 2 to 50 employees).

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 proposed rule.

1. Estimation Methods and Sources of Uncertainty

HHS estimates 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 HHS 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.

HHS conducted research to compile information regarding the regulatory structure in place by State and market. HHS 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 carriers and filings in the individual and small group markets. In its original estimate for the number of filings, HHS 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.

HHS 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 HHS 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, HHS 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 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. HHS has determined that there is insufficient data to estimate the number of rate filings beyond 2011.

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 HHS 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 are 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 HHS 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 proposed rule. Given the combination of data imperfections and

limitations and behavioral uncertainties, HHS 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, HHS estimates a range of rate filings from 3,635 to 4,015 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.⁵ Based on actuarial estimates using data from 2009 and 2010, HHS estimates that the number of 2011 rate filings will be in the range of from 4,858 to 5,828 (see Table 3).

Issuers are not required to submit preliminary justification 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

⁵ 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.

to be 20 to 42 percent in 2011. HHS 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 would 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 proposed 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

2010.⁶ The fraction of enrollees in plans requesting an increase of 10 percent or greater ranged from 34 percent to 77 percent. HHS 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).⁷ 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. HHS 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, HHS estimates 15 percent, 30 percent, and 50 percent.⁸

The following table (Table 3) shows the low, mid and high range estimates (371, 773, and 1,396) 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	1107	3751	4858
Mid Range	1247	4097	5343
High Range	1386	4442	5828
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	443	750	1193
Mid Range	673	1229	1902
High Range	929	1866	2794
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	221	150	371
Mid Range	404	369	773
High Range	650	746	1396

F. Estimated Administrative Costs Related To Rate Review Provisions

As stated earlier in this preamble, this proposed rule would implement the reporting requirements of section 2794, describing the type of information that would be included in the preliminary justification to the Secretary and the applicable State and the disclosure that would be made available to consumers on the issuer's Web site if the rate increase is found to be unreasonable.

⁶ 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/IMMHPFRFR.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;

HHS has quantified the primary sources of start-up costs that issuers in the individual and small group market would incur to bring themselves into compliance with this proposed rule, as well as the ongoing annual costs that they would incur related to these requirements. These costs and the methodology used to estimate them are discussed below.

In order to assess the potential administrative burden relating to the requirements in this proposed rule, HHS

consulted with the NAIC and industry experts to gain insight into the tasks and level of effort required. Based on these discussions, HHS estimates that issuers would incur one-time start-up costs associated with developing teams to review the requirements in this proposed rule, and developing processes for capturing the necessary data (e.g., automating systems). HHS estimates that issuers would also incur ongoing annual costs relating to data collection, completing the justification

⁷ 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.

⁸ Rate filings in which each of the products covered in the filing are grandfathered plans will not be subject to the provisions of this proposed rule. However, in the small group market, HHS 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 proposed rule.

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 proposed 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 would 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.

HHS estimates that the one-time costs relating to the rate review reporting requirements in this proposed rule would range from \$10 million to \$15 million, and that annual costs would be between \$0.4 million and \$4.5 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	371	52,125	\$200	\$10,425,000	\$25,000	\$28,100
Ongoing Costs	417	371	2,226	200	445,200	1,068	1,200
Total Year One Costs	417	371	54,351	200	10,870,200	26,068	29,300
MID RANGE ASSUMPTIONS:							
One-Time Costs	417	773	62,550	200	12,510,000	30,000	16,184
Ongoing Costs	417	773	8,503	200	1,700,600	4,078	2,200
Total Year One Costs	417	773	71,053	200	14,210,600	34,078	18,384
HIGH RANGE ASSUMPTIONS:							
One-Time Costs	417	1,396	72,975	200	14,595,000	35,000	10,455
Ongoing Costs	417	1,396	22,336	200	4,467,200	10,713	3,200
Total Year One Costs	417	1,396	95,311	200	19,062,200	45,713	13,655

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 to, in conjunction with the States 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, HHS estimates that the additional costs to the States will be negligible given that the majority already conduct 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 proposed regulation. If a State does not have an effective rate review program in place for all or some markets within the State, HHS would 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, HHS estimates a range between 28 percent and 36 percent of the rate filings requiring review in 2011 would fall under HHS's review responsibility. Based on these filing estimates and the necessary actuarial expertise, this rate review process would range in cost from \$0.6 million to \$4.8 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

TABLE 5—ESTIMATED ACTUARIAL RATES—Continued

Estimated actuarial rates	Low	Mid	High
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	104	255	503
Total Expected Contracting Cost	551,720	1,835,490	4,826,285

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

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

HHS estimates that the cost burden on States would be small because most States currently conduct rate review. For these States the incremental costs and requirements of this regulation would 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 HHS. 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 would be required to report on their rate review activities to the Secretary. HHS believes that this reporting requirement will involve minimal cost. HHS estimates that

reporting information from the State to Department will require approximately 20 minutes per filing. Based on resource use from the NAIC's 2009 Resource Report which shows the average Department of Insurance actuary earns approximately \$45 an hour, HHS estimates an average cost per filing of \$15. The estimated cost of reporting the two-thirds of filings meeting or exceeding the 10 percent threshold, which are reviewed by States, ranges from \$4,011 to \$13,404.

G. Transfers

The proposed 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 proposed 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.⁹

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

⁹Data provided by States on recent rate review actions from informal discussions between HHS and State Department of Insurance actuaries

in these States will be less than in States currently without strong rate review.

Although HHS did not estimate the impact of this proposed regulation on the reduction in premium rate increases, HHS 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, HHS 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, HHS invites comments on how to calculate premium savings so as to determine whether the \$100 million threshold is met.

H. Regulatory Alternatives

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

If HHS established a threshold lower than 10 percent, this would impose a larger burden on issuers, States, and HHS, and HHS judged that it would not yield a substantial benefit for consumers. However, as discussed earlier in the preamble, HHS proposes an approach that balances the regulatory burdens on both the agency and the industry where every rate increase, no matter how small, is reviewed for unreasonableness against the potential

harm to consumers should a small but unreasonable increase be implemented.

In addition, HHS 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 such 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.

HHS 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, HHS considered the cost benefit of the additional Federal resources to potentially catch unjustified/unreasonable rates vs. fairness to consumers and the additional administrative burden for insurers. HHS could spend additional resources and potentially catch only a small number of unreasonable rates below the threshold.

HHS 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, HHS 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 State-Specific Threshold

HHS recognizes that underlying costs and health care trends vary from State to State. Many factors influence the magnitude and frequency of increases in the States, and a single, national filing threshold does not reflect all of the local variations. Therefore, in this proposed rule, HHS proposes to use a State-specific threshold as determined by the Secretary for future calendar years.

HHS did not immediately adopt the State-specific threshold for rate increases in calendar year 2011 because of the lack of State-specific data. For future calendar years, the Secretary would consider the State-specific data submitted for each rate increase subject to review, and also the State-specific rate trend data and information received by the Secretary from those States that have received "premium review grants" under section 2794(c) of the PHS Act. Using these data, the Secretary may set a State-specific threshold. In the event the Secretary does not have sufficient data to calculate a State-specific

threshold, the threshold will remain at 10 percent.

3. 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 received 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, HHS decided to propose a uniform threshold for all insurers, regardless of their size.

4. Apply Rate Review Standards to the Large Group Market

As discussed in the preamble, HHS discussed applying this proposed rule to the large group market as well as the individual and small group markets. However, because of the current rate-setting practices of the large group market and States' limited authority over this segment of the market, HHS concluded that this regulation should only apply to the individual and small group markets.

We welcome comments on the likely costs and benefits of this proposed rule as presented, on alternatives that would improve consumer benefits and minimize industry burden, and on our quantitative estimates of burden.

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 proposed 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"). HHS 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 proposed 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 proposed rule are approximately \$25 thousand per covered entity (regardless of size or non-profit status) and approximately \$4 thousand 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 proposed 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 proposed 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 notice of proposed rulemaking would not affect small rural hospitals. Therefore, the Secretary has determined that this proposed rule would 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 proposed 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 2010, that threshold level is approximately \$135 million.

UMRA does not address the total cost of a proposed 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 proposed rule includes no mandates on State, local, or tribal governments. Under the proposed rule, issuers would be required to submit rate justification reports for rate increases of 10 percent or greater directly to HHS. 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 HHS the final determination and an explanation of its analysis. However, if a State chooses not to do so, HHS 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 notice for proposed rulemaking 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 HHS’ view, while the requirements proposed in this notice for proposed rulemaking would not impose substantial direct costs on State and local governments, this notice for proposed rulemaking 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.

HHS recognizes that there are federalism implications with regard to HHS’ evaluation of effective rate review programs and its subsequent review of rate increases. Under Subpart C of this

proposed rule, HHS outlines those criteria that States would have to meet in order to be deemed to have an effective rate review program. If HHS determines that a State does not meet those criteria, then HHS would review a rate increase subject to review to determine whether it is unreasonable. If a State does meet the criteria, then HHS 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 would likely be deemed effective and satisfy the requirements under this proposed 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, HHS 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, and consulting with State insurance officials on an individual basis.

Throughout the process of developing this notice of proposed rulemaking, HHS 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 HHS’ 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, HHS certifies that the Office of Consumer Information and Insurance Oversight has complied with the requirements of Executive Order 13132 for the attached notice for proposed rulemaking 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 proposes to amend 45 CFR subtitle A, subchapter B, by adding a new 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 HHS or by a State.
154.215 Submission of disclosure to HHS
for rate increases subject to review.
154.220 Timing of preliminary justification.
154.225 Determination by HHS 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 HHS's determinations of effective
rate review programs.

Authority: Section 2794 of the Public
Health Service Act (42 U.S.C. 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 small group or
individual health insurance coverage to
report information concerning
unreasonable rate increases to the
Department of Health and Human
Services (HHS). 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:

Effective rate review program means a
State program that HHS has determined
meets the requirements set forth in
§ 154.301(a) 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.

HHS means the Department of Health
and Human Services.

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 an 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 HHS is conducting the
review required by this part, a rate
increase that HHS determines is:
- (i) An excessive rate increase;
 - (ii) An unjustified rate increase; or
 - (iii) An unfairly discriminatory rate
increase; as described in § 154.205.
- (2) When HHS 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 paragraph (1) of
subsection (c) of section 2791 of the
Public Health Service Act, or as
described in paragraph (2), (3) or (4) of
such subsection if the benefits are
provided under a separate policy,
certificate or contract of insurance.

**Subpart B—Disclosure and Review
Provisions**

**§ 154.200 Rate increases subject to
review.**

(a) Rate increases that meet or exceed
the following threshold are subject to
review to determine whether they are
unreasonable rate increases:

(1) For rate increases filed in a State
on or after July 1, 2011, or effective on
or after July 1, 2011 in a State that does
not require rate increases to be filed, a
rate increase that is 10 percent or more,
as calculated under paragraph (b) of this
section.

(2) For rate increases filed in a State
during calendar year 2012 and
thereafter, or effective during calendar
year 2012 and thereafter in a State that
does not require rate increases to be
filed, any rate increase, as calculated
under paragraph (b) of this section that
meets or exceeds:

(i) State-specific thresholds as
determined by the Secretary for the
applicable calendar year based on the
cost of health care and health insurance
coverage in a State; or

(ii) 10 percent if an applicable State-
specific threshold is not established by
the Secretary under paragraph (a)(2)(i)
of this section. The thresholds set forth
in paragraph (a)(2)(i) will be published
in the Federal Register no later than
September 15th of the year preceding
the calendar year in which the threshold
applies, beginning in 2012.

(b) A rate increase meets or exceeds
the applicable threshold set forth in
paragraph (a) of this section if the
weighted average increase for all
enrollees subject to the rate increase
meets or exceeds the applicable
threshold.

(c) If a rate increase that does not
otherwise meet or exceed the threshold
under paragraph (b) of this section
meets or exceeds the threshold if
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 HHS reviews a rate increase
subject to review under § 154.210(a),
HHS 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, HHS 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 HHS 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 HHS or by a State.

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

(b) HHS 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 HHS, on a form and in a manner prescribed by the Secretary, its final determination of whether a rate increase is unreasonable, which must include an 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) HHS will post and maintain on its Web site a list of the States that meet the

requirements of paragraph (b) of this section.

§ 154.215 Submission of disclosure to HHS 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;

(2) Written description justifying the rate increase; and

(3) When HHS is reviewing the rate increase under § 154.210(a), rate filing documentation.

(c) A health insurance issuer must complete and submit parts one and two of the preliminary justification described in paragraph (b)(1) and (2) of this section to HHS 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 HHS is reviewing the rate increase under § 154.210(a), then the health insurance issuer must also complete and submit part three of the preliminary justification described in paragraph (b)(3) of this section to HHS 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.* The rate increase summary must include the following:

(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.

(f) *Content of written description justifying the rate increase.* 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 rating methodology;

(2) 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

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

(g) *Content of rate filing documentation.* (1) The rate filing documentation supports the information required under paragraphs (d) and (e) of this section. This documentation must be sufficient to permit HHS to conduct a review to determine whether the rate increase is an unreasonable rate increase and must include the following:

(i) Description of the type of policy, benefits, renewability, general marketing method and issue age limits;

(ii) Scope and reason for the rate increase;

(iii) Average annual premium per policy, before and after the rate increase;

(iv) Past experience, and any other alternative or additional data used;

(v) A description of how the rate increase was determined, including the general description and source of each assumption used;

(vi) The cumulative loss ratio and a description of how it was calculated;

(vii) The projected future loss ratio and a description of how it was calculated;

(viii) The projected lifetime loss ratio that combines cumulative and future experience, and a description of how it was calculated;

(ix) Federal medical loss ratio standard in the applicable market to which the rate increase applies, accounting for any adjustments allowable under Federal law; and

(x) If the result under paragraph (g)(1)(vii) of this section is less than the standard under paragraph (g)(1)(ix) of this section, a justification for this outcome.

(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, HHS will accept a copy of the filing provided that the filing includes all of the information described in paragraph (g)(1)(i) through paragraph (g)(1)(x) of this section.

(h) In the event the level of detail provided by the issuer for the information under paragraph (g) of this section does not provide sufficient basis

for HHS to determine whether the rate increase is an unreasonable rate increase, HHS will request the additional information necessary to make its determination. The health insurance issuer must provide the requested information to HHS within five business days following its receipt of the request.

(i) *Posting of the disclosure on the HHS Web site.*

(1) HHS will promptly make available to the public on its Web site the information contained in parts one and two of each preliminary justification.

(2) HHS will make available to the public on its Web site the information contained in part three of each preliminary justification after its receipt thereof.

(i) HHS will post any information contained in part three of the preliminary justification that is not designated as "confidential" as defined in HHS's Freedom of Information Act regulations, 45 CFR 5.65.

(ii) HHS will make a determination as to whether to post information designated as "confidential" under the standards and procedure set forth in 45 CFR 5.65, and will post that information only after making a determination that it is subject to disclosure as provided by 45 CFR 5.65.

(3) HHS will include the following disclaimer on its Web site with information made available to the public under this paragraph (i):

"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."

§ 154.220 Timing of 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 July 1, 2011, or effective on or after July 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 HHS 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 HHS and the State the preliminary justification prior to the implementation of the rate increase.

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

(a) When HHS receives a preliminary justification for a rate increase subject to review and HHS reviews the rate increase under § 154.210(a), HHS will determine whether the rate increase is an unreasonable rate increase.

(1) HHS will post on its Web site its final determination and a brief explanation of its analysis within five business days following its final determination.

(2) If HHS determines that the rate increase is an unreasonable rate increase, HHS 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), HHS will adopt the State's determination of whether a rate increase is unreasonable and post on the HHS 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, HHS will provide the State's final determination and brief explanation to the health insurance issuer within five business days following HHS's receipt thereof.

§ 154.230 Submission and posting of final justifications for unreasonable rate increases.

(a) If a health insurance issuer receives from HHS a final determination by HHS 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 HHS 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 HHS or a State to be unreasonable, the health insurance issuer must, within the later of 10 days after the

implementation of such increase or the health insurance issuer's receipt of HHS's final determination that a rate increase is an unreasonable rate increase:

(1) Submit to HHS a final justification in response to HHS'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 HHS and described in § 154.215(i);

(ii) HHS'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 HHS 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) HHS will post all final justifications on the HHS Web site. This information will remain available to the public on the HHS Web site for three years.

Subpart C—Effective Rate Review Programs

§ 154.301 HHS's determinations of effective rate review programs.

(a) *Effective rate review program.* The purpose of an effective rate review program as set forth in this section is to determine whether a rate increase is an unreasonable rate increase. In evaluating whether a State has an effective rate review program, HHS 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 include an analysis of:

(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 risk-based capital status relative to national standards.

(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) HHS will determine whether a State has an effective rate review program for each market based on documentation and information

received from the State or any other information otherwise available to HHS that its rate review program meets the criteria described in paragraph (a) of this section.

(c) HHS reserves the right to determine that a State no longer has an effective rate review program if HHS determines that the State no longer satisfies the criteria set forth in paragraph (a) of this section.

Dated: December 16, 2010.

Jay Angoff,

Director, Office of Consumer Information and Insurance Oversight.

Approved: December 16, 2010.

Kathleen Sebelius,

Secretary.

[FR Doc. 2010-32143 Filed 12-21-10; 8:45 am]

BILLING CODE 4150-03-P