

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 144 and 147

CMS-9981-P

RIN 0950-AA20

Student Health Insurance Coverage

AGENCY: Centers for Medicare & Medicaid Services (CMS),
HHS.

ACTION: Proposed rule.

SUMMARY: This document contains a proposed regulation that would establish rules for student health insurance coverage under the Public Health Service Act and the Affordable Care Act. The proposed rule would define "student health insurance coverage" as a type of individual health insurance coverage, and, pursuant to section 1560(c) of the Affordable Care Act, specify certain Public Health Service Act and Affordable Care Act requirements as inapplicable to this type of individual health insurance coverage.

DATES: Send your comments on or before **[OFR: INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: In commenting, please refer to file code CMS-9981-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

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

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-9981-P,
P.O. Box 8010,
Baltimore, MD 21244-8010.

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

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-9981-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

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

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

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

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

Comments mailed to the addresses 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 "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

For questions concerning this proposed rule, contact Lisa Campbell or Robert Imes, Center for Consumer Information and Insurance Oversight, Department of Health and Human Services, by phone at (301) 492-4489.

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 be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

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 of 2010 (Pub. L. 111-152) was enacted on March 30, 2010. In this proposed rule 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 (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. Interim final rules published in 2010 by the three Departments included those that implemented PHS Act sections 2711 (regarding lifetime and annual dollar limits on benefits) and 2719A (regarding patient protections) (75 FR 37188 (June 28, 2010)), and section 2713 (regarding preventive health services) (75 FR 41726 (July 19, 2010)). HHS published interim final rules implementing section 2718, regarding medical loss ratio (75 FR 74864 (December 1, 2010)). A full list of the regulations, as well as guidance published by the Departments regarding various issues related to the implementation of the Affordable Care Act, is also available at <http://www.hhs.gov/ccio> and <http://www.dol.gov/ebsa>.

Pursuant to the Affordable Care Act which requires that "[N]othing in this title (or an amendment made by this title) shall be construed to prohibit an institution of higher education (as such term is defined for purposes of the Higher Education Act of 1965) from offering a student health insurance plan, to the extent that such requirement is otherwise permitted under applicable Federal, State, or local law," this proposed regulation would define the term

“student health insurance coverage” as a specific type of individual health insurance coverage, and would render certain requirements of the PHS Act and the Affordable Care Act as inapplicable to student health insurance coverage, given their unique characteristics.

II. Provisions of the Proposed Rule

A. Introduction

The U.S. Government Accountability Office (GAO) has estimated that most students enrolled in U.S. colleges and universities have health coverage through employer-sponsored plans, but approximately 7 percent of students between ages 18 and 23, around 610,000 individuals, were covered through other private insurance such as student health insurance plans in 2006.¹ Industry estimates put the number of individuals with student health insurance coverage significantly higher, at 1.1 to 1.5 million individuals. This may be explained, in part, by the industry estimates counting university students of all ages, not just those between ages 18 and 23. Furthermore, older students may be more likely to have dependents enrolled under their student health insurance coverage.

¹ U.S. Government Accountability Office, *Most College Students Are Covered through Employer-Sponsored Coverage, and Some Colleges and States are Taking Steps to Increase Coverage*, Report 08-389 (March 2008).

Altogether, according to industry sources, 1,500-2,000 institutions of higher education offer student health coverage. While the same sources estimate that 200,000 individuals have coverage through student health plan arrangements that are self-funded through colleges or universities, the vast majority of student plans are insured.

This generally means that a health insurance issuer contracts with a college or university to issue a group or an association "blanket" health insurance policy at a negotiated cost for a defined set of benefits for each student who desires coverage. While the contract between the issuer and the college or university usually covers multiple years, the contract can be modified on an annual basis to make minor benefit design modifications and to adjust the price for inflation. The policy is generally rated on a group basis based on the total expected claims experience of the college or university's students enrolled in the plan. Students of the college or university, in turn, are eligible to buy into the policy either on an academic term basis or an annual basis.

Insured student health insurance plans fall under the regulatory authority of the States and the Federal government pursuant to the PHS Act. Since these student

health insurance plans are not employment-based, they do not meet the definition of a group health plan under PHS Act section 2791(a)(1),² even though some States regulate such plans, for purposes of State law, as types of group coverage (non-employer group coverage or association "blanket coverage").

Concerns have been raised about the quality and value of these plans in some cases. For example, the Attorney General of New York in April 2010 released the findings of an investigation that concluded in part that some student health plans have such low coverage limits, exclusions, and limited benefits that they place students and their families at risk for catastrophic costs for medical care.

The benefits provided by student health plans vary widely. For example, the GAO study found annual limits ranging from \$15,000 to \$250,000, with the median being \$50,000.

Given the variation in benefit designs for student health insurance coverage, premiums vary significantly. The GAO found annual premiums that ranged from \$28 to \$2,397, with the average being \$850.

² The definition of "group health plan" in PHS Act section 2791(a)(1) incorporates the definition of an employee welfare benefit plan under the Employee Retirement Income Security Act (ERISA) of 1974, section 3(1).

With the passage of the Affordable Care Act, several issues have arisen regarding the applicability of the PHS Act and the Affordable Care Act to student health insurance plans. Section 1560(c) of the Affordable Care Act provides that "[N]othing in this title (or an amendment made by this title) shall be construed to prohibit an institution of higher education (as such term is defined for purposes of the Higher Education Act of 1965) from offering a student health insurance plan, to the extent that such requirement is otherwise permitted under applicable Federal, State, or local law." Were certain provisions of the Affordable Care Act applied to student health insurance coverage, we believe it would effectively prohibit institutions of higher education from being able to offer these plans. Because section 1560(c) of the Affordable Care Act instructs HHS not to construe any provisions of the Affordable Care Act to have this effect, this rule discusses which provisions we propose construing not to apply to student health insurance coverage pursuant to section 1560(c).

B. Definition of Student Health Insurance Coverage

The proposed regulation would define student health insurance coverage as a type of individual health insurance coverage provided pursuant to a written agreement between

an institution of higher education (as defined in the Higher Education Act of 1965) and a health insurance issuer, which is provided to students who are enrolled in that institution and their dependents. In addition, the definition would require that the coverage only be made available to students enrolled at the institution of higher education and their dependents; that eligibility for coverage could not be conditioned on any health status-related factor; and that it would have to satisfy any additional requirement that may be imposed under State law.

For purposes of the PHS Act, health insurance coverage that is not provided in connection with an employer-based group health plan is individual market coverage, notwithstanding that applicable State law might classify such non-employer group coverage as association blanket or discretionary group coverage. Previously, in the preamble to the interim final regulations implementing the individual market requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Department clarified that "college plan" coverage for students was individual market coverage, as distinguished from the group health plans provided to college employees. 62 FR 16985, 16992 (April 8, 1997).

As noted earlier in the introduction, it is believed that there are a small number of self-funded student health plans. The PHS Act and the Affordable Care Act give HHS regulatory authority over health insurance issuers in the group and individual markets and over non-federal governmental group health plans. Because self-funded student health plans are neither health insurance coverage nor group health plans, as those terms are defined in the PHS Act, HHS has no authority to regulate them. Nonetheless, these self-funded student health plans may be regulated by the States. The Department invites comments on the prevalence, structure, and State regulation of these self-funded student health plans.

Under the proposed regulation, the term "student health insurance coverage" would be defined to include only insurance provided pursuant to a written agreement between an institution of higher education and a health insurance issuer. As proposed, the agreement could be evidenced by the health insurance issuer issuing the master insurance policy to the institution of higher education. If the institution of higher education is not the policyholder (that is, the students themselves are the policyholders), we proposed to require that in order to meet the definition of student health insurance coverage, there would have to

be a separate agreement between the issuer and the institution of higher education clearly indicating the institution of higher education's role with respect to factors such as selecting, terminating, and replacing the health insurance issuer; choosing or negotiating policy terms; setting student and dependent eligibility terms; publicizing, endorsing, or recommending the policy to students and dependents; and/or providing students and dependents with assistance with obtaining benefits or appealing denials under the coverage. Under the proposed rule, if there were no written agreement between the institution of higher education and the health insurance issuer, such coverage would be subject to all of the individual market requirements in the PHS Act and the Affordable Care Act.

The definition of student health insurance coverage in this proposed regulation would be intended to ensure that student health insurance coverage is offered only to students enrolled in an institution of higher education. Student health insurance coverage also could cover students' dependents such as their spouses and children, as defined by the plan terms.

In addition, we propose that coverage that otherwise met the definition of student health insurance coverage

could still meet the definition even if it also provided coverage for limited periods of time to individuals who are on breaks between academic terms, on temporary leaves of absence for medical or other reasons, or have recently graduated or otherwise ceased enrollment in an institution of higher education. The institution of higher education and the issuer would specify in the documents governing the student health insurance coverage which individuals could be viewed as being enrolled in the institution of higher education for purposes of eligibility for the student health insurance coverage.

Past research suggests that institutions of higher education vary in the extent to which part-time students are offered student health insurance coverage.³ This proposed regulation would not set any minimum threshold for determining student status under student health insurance coverage (for example, require that students take a minimum number of course hours each term or be seeking a degree), leaving such eligibility decisions to each institution of higher education and the issuer.

³ For example, U.S. Government Accountability Office, *Most College Students Are Covered through Employer-Sponsored Coverage, and Some Colleges and States are Taking Steps to Increase Coverage*; Stacey Pogue, *Covering Uninsured Students in Texas: The Role of Student Health Insurance Coverage* (2005).

The proposed regulation would provide that coverage offered to non-students seeking individual market coverage would not meet the definition of student health insurance coverage. Other individual market coverage that incidentally covers a student (such as under a parent's family policy) would not meet the definition of student health insurance coverage under this proposed regulation.

Lastly, under this proposed regulation, in order to meet the definition of student health insurance coverage, the coverage could not condition enrollment on any health status-related factor of a student or dependent. The term "health status-related factor" or "health factor" is proposed to have the same meaning as that term has in 45 CFR §144.103, incorporating 45 CFR §146.121(a), which applies with respect to group health insurance requirements. That term includes health status, medical condition (including both physical and mental illnesses), claims experience, receipt of health care, medical history, genetic information, evidence of insurability, and disability. Incorporation of this non-discrimination requirement is modeled on the definition of bona fide association coverage in 45 CFR §144.103. HHS believes that this requirement will have a minimal impact on student health insurance plans because the Department understands

that, in the past, student health insurance coverage offered by institutions of higher education receiving Federal funds generally has not discriminated against individual students or dependents on the basis of health status due to requirements under section 504 of the Rehabilitation Act of 1973 and related regulations issued by the U.S. Department of Education that prohibit discrimination based on disability.⁴

C. Student Health Insurance Coverage and Short-Term Limited Duration Insurance

45 CFR §144.103 defines short-term limited duration insurance as "health insurance coverage provided pursuant to a contract with an issuer that has an expiration date specified in the contract (taking into account any extensions that may be elected by the policyholder without the issuer's consent) that is less than 12 months after the original effective date of the contract." Short-term limited duration insurance is available to individuals to fill in gaps of coverage that otherwise might occur, such as when they are between jobs and without employer coverage. Since short-term limited duration insurance is specifically excluded from the definition of individual

⁴ "No qualified handicapped student shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any... health insurance... to which this subpart applies." 34 CFR § 104.43(a).

health insurance coverage in 45 CFR §144.103, the individual market protections of the PHS Act and the Affordable Care Act do not apply to short-term limited duration insurance.

In many student health insurance plans, the term of the coverage is for a period less than 12 months- sometimes for only a day or even minutes less than 12 months- suggesting an intent to claim short-term limited duration insurance status and avoid PHS Act and Affordable Care Act requirements.⁵ However, we understand that some of these policies are also renewable at the option of the student so long as the student continues enrollment at the school. In fact, in some instances, the student's college or university will automatically re-enroll the student in such coverage without any affirmative action on the student's part.

It is our understanding that, in the past, student health insurance coverage was considered in some cases by issuers and institutions of higher education to be short-term limited duration insurance if the initial term of the coverage was less than 12 months in duration, even if it renewed automatically. Accordingly, many student health

⁵ For example, the Department noted one student health insurance policy that was effective from 12:01 A.M., August 1, to 11:59 P.M., July 31 of the following year. Other policies had similar policy periods.

insurance plans do not provide some important protections of the PHS Act and the Affordable Care Act that apply to individual health insurance coverage. The proposed regulation would clarify that if the coverage is renewable each year at the option of the student as long as the student remains in school, the renewals would constitute "extensions that may be elected by the policyholder without the issuer's consent" that would not expire within a year, and that the coverage would not, therefore, meet the definition of short-term limited duration insurance. We understand that the right to renew the insurance coverage, provided that the student remains in school, is a common practice for student health insurance coverage. Thus, this proposed regulation would clarify that student health insurance coverage that is at least 12 months in duration, including any potential extension that may be elected by the student, is individual health insurance coverage generally subject to the individual market requirements of the PHS Act and the Affordable Care Act. This proposed regulation would not amend the existing definition of short-term limited duration insurance. HHS invites comments on the prevalence of existing student health insurance plans that meet the definition of short-term limited duration insurance and whether such plans should be

subject to certain requirements of the PHS Act and the Affordable Care Act.

D. Application of the PHS Act and the Affordable Care Act

In clarifying the general applicability of the PHS Act and the Affordable Care Act to student health insurance plans, this proposed regulation would also specify that a limited number of requirements of the PHS Act and the Affordable Care Act are inapplicable to student health insurance coverage. Section 1560(c) of the Affordable Care Act provides that "[N]othing in this title (or an amendment made by this title) shall be construed to prohibit an institution of higher education (as such term is defined for purposes of the Higher Education Act of 1965) from offering a student health insurance plan, to the extent that such requirement is otherwise permitted under applicable Federal, State, or local law." The Department interprets this provision of the Affordable Care Act to mean that if particular requirements in the Affordable Care Act would, as a practical matter, have the effect of prohibiting an institution of higher education from offering a student health plan otherwise permitted under Federal, State or local law, such requirements would be inapplicable pursuant to the rule of construction in section 1560(c).

The Department has identified several provisions in the PHS Act and the Affordable Care Act that we believe would have this effect and several others that might have this effect.

For example, the PHS Act guaranteed availability and guaranteed renewability requirements are incompatible with plans that, by definition, are restricted to individuals enrolled as students in institutions of higher education and their dependents. As explained below, the proposed regulation would construe these provisions as inapplicable to student health insurance coverage, for purposes of Federal law, so as to avoid conflict with section 1560(c) of the Affordable Care Act. The PHS Act and implementing regulations make clear that guaranteed issue and guaranteed renewability requirements are inapplicable to bona fide association plans that, like student health plans, are limited by definition to a defined pool of beneficiaries. This rule proposes to construe student health insurance coverage to be offered through a bona fide association for this purpose.⁶

Under this proposed regulation, student health insurance coverage would be subject to the individual

⁶ See 45 CFR §§148.120(g)(2) and 148.122(c)(5), which exempts bona fide associations from the guaranteed issue and guaranteed renewability requirements, respectively.

market requirements of the PHS Act and the Affordable Care Act, with the exception of those specific provisions that are identified in this proposed rule. The specific provisions which would be inapplicable to student health plans are discussed below. We also discuss other Affordable Care Act requirements that may so impede the offering of student health plans that they may also be found inapplicable pursuant to section 1560(c) of the Affordable Care Act. We solicit comments as to whether this is the case with respect to these latter requirements.

1. Guaranteed Availability and Guaranteed Renewability

Section 2741(a) of the PHS Act generally requires health insurance issuers that offer coverage in the individual market in a State to offer coverage to certain eligible individuals,⁷ and prohibits imposing any preexisting condition exclusion with respect to such individuals.⁸

Section 2742 of the PHS Act requires a health insurance issuer that provides individual health insurance

⁷ For purposes of PHS Act sections 2741 and 2744, an eligible individual is defined in PHS Act section 2741(b). These eligible individuals, also referred to as "HIPAA eligible" individuals, meet certain criteria including having recently lost group health coverage and having at least 18 months of prior creditable coverage. See 45 CFR §§ 148.103 through 148.128.

⁸ We note that the guaranteed availability requirement of PHS Act section 2741(a)(1) does not apply in States that are implementing an acceptable alternative mechanism for HIPAA eligible individuals under section 2744 of the PHS Act. In those States, State law provides alternative ways to guarantee coverage to eligible individuals. We doubt that such mechanisms require student health insurance coverage to be sold to HIPAA eligible individuals who otherwise would not qualify. However, if they do, we encourage such States to revise their mechanisms so that it would not be required.

coverage to any individual to renew or continue the coverage in force at the option of the individual. This requirement applies regardless of whether the policyholder obtained the coverage as an eligible individual.

As previously indicated, both the guaranteed availability and guaranteed renewability requirements provide an exception for coverage that is offered through a bona fide association. (See PHS Act sections 2741(e)(1) and 2742(b)(5) and §§148.120(g)(2) and 148.122(c)(5).)⁹

Because application of the guaranteed issue and guaranteed renewability requirements would be inconsistent with the provision of student health plans, this proposed regulation would construe student health insurance coverage for purposes of Federal law as falling within the bona fide association exception as provided in PHS Act sections 2741(e)(1) or 2742(b)(5). Such plans, by definition, meet the criteria described in sections (2) through (5) of the definition of a bona fide association, contained in 45 CFR §144.103. This is because student health insurance coverage is provided in a manner similar to a bona fide association

⁹ Section 2741(e)(1) of the PHS Act provides that "the provisions of subsection (a) of this section shall not be construed to require that a health insurance issuer offering health insurance coverage only . . . through one or more bona fide associations . . . offer such health insurance coverage in the individual market." Section 2742(b)(5) of the PHS Act provides that, in the case of health insurance coverage that is made available in the individual market only through one or more bona fide associations, the membership of the individual in the association ceases but only if such coverage is terminated under this paragraph uniformly without regard to any health status-related factor of covered individuals.

since it only offers enrollment to a closed class of similarly situated individuals (that is, students and their dependents) and is only renewable to individuals who remain enrolled in colleges and universities as students and their dependents.¹⁰

In construing student health insurance coverage as bona fide association plans for purposes of these two sections of the PHS Act, we do not propose to apply the first criterion in §144.103, which is that the association must have been actively in existence for at least five years. That criterion is designed to reinforce the requirement that an association has been formed for purposes other than obtaining insurance. However, since it is highly unlikely that an institution of higher education would, or even could, be formed only for the purpose of obtaining insurance, we do not believe it is necessary to bar institutions of higher education that have not yet been

¹⁰ The full definition of a bona fide association is as follows: *Bona fide association* means, with respect to health insurance coverage offered in a State, an association that meets the following conditions:

- (1) Has been actively in existence for at least 5 years.
- (2) Has been formed and maintained in good faith for purposes other than obtaining insurance.
- (3) Does not condition membership in the association on any health status-related factor relating to an individual.
- (4) Makes health insurance coverage offered through the association available to all members regardless of any health status-related factor relating to the members (or individuals eligible for coverage through a member)
- (5) Does not make health insurance coverage offered through the association available other than in connection with a member of the association.
- (6) Meets any additional requirements that may be imposed under State law.

in existence for five years from providing student health insurance coverage.

We would also note that the sixth criterion (meets any additional requirement imposed by State law) simply duplicates one of the criteria under the proposed definition of student health insurance coverage, so it would also be construed to be satisfied for this purpose.

This would be an automatic, construed status for purposes of Federal law, intended solely to allow student health insurance coverage to be limited to students and their dependents, without imposing any availability requirements for non-students, or renewability requirements after an individual has ceased to be a student, similar to how bona fide association coverage is limited to association members. This construed status does not require health insurance issuers offering student health insurance coverage to revise or amend their current business or marketing agreements and practices.

2. Annual Limits

Section 2711 of the PHS Act prohibits group health plans and health insurance issuers offering group or individual health insurance coverage from establishing lifetime limits on the dollar value of essential health

benefits¹¹ and restricts annual dollar limits on such benefits before 2014 for group health plans and non-grandfathered individual market plans. For plan or policy years beginning on or after January 1, 2014, annual dollar limits will be prohibited on essential health benefits. Interim final regulations published on June 28, 2010 implement the prohibition on lifetime dollar limits and set forth restrictions on annual dollar limits that apply prior to 2014 (75 FR 37188). Under the annual limits interim final regulations, annual limits on the dollar value of essential health benefits generally cannot be lower than: \$750,000 for plan or policy years beginning on or after September 23, 2010 but before September 23, 2011; \$1.25 million for plan or policy years beginning on or after September 23, 2011 but before September 23, 2012; and \$2 million for plan or policy years beginning on or after September 23, 2012 but before January 1, 2014.

Many issuers that have provided student health insurance coverage customarily imposed low annual limits on the student health insurance coverage, and this practice

¹¹ Section 1302(b) of the Affordable Care Act defines essential health benefits to "include at least the following general categories and the items and services covered within the categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care."

apparently continued after the enactment of the Affordable Care Act and publication of the interim final rules because of the view by issuers that many of these policies were not subject to the Affordable Care Act because they were short-term limited duration insurance. As noted above, for plan years beginning after September 23, 2011, the minimum annual limit is \$1.25 million, a level which, if applied immediately to student health insurance coverage, is so much higher than many current limits that it could serve to "prohibit an institution of higher education... from offering a student health insurance plan." In order to avoid this and be consistent with section 1560(c) of the Affordable Care Act, HHS is proposing to provide a transition period for issuers of student health insurance coverage to comply with the annual limits requirements in 45 CFR §147.126. The transition period would be for policy years beginning before September 23, 2012. For that period, however, students and their dependents should have protection from being subjected to extremely low annual dollar limits on essential health benefits. Accordingly, student health insurance coverage would be required to have an annual limit of no less than \$100,000 on essential benefits for policy years beginning on or after January 1, 2012 but before September 23, 2012. HHS believes that issuers of

student health insurance coverage should be able to fully comply with the annual dollar limits requirements of not lower than \$2 million for policy years beginning on or after September 23, 2012 without incurring undue financial hardship or without disruption to the student health insurance market given the period of time provided under this proposed rule for them to comply with the requirements. HHS is requesting comments on the applicability of the annual dollar limits requirements to student health insurance coverage, and the proposed phase-in of the annual dollar limits requirements.

Lastly, under the proposed regulation, the prohibition on lifetime limits under section 2711 of the PHS Act would be applicable to student health insurance coverage.

3. Coverage of Preventive Services

Section 2713 of the PHS Act requires that a group health plan and a health insurance issuer offering group or individual health insurance coverage provide benefits for specified recommended preventive services and prohibits the imposition of cost-sharing requirements with respect to such services. Interim final regulations published on July 19, 2010, implemented rules for preventive health services (75 FR 41726). Concerns have been raised as to whether

certain administrative fees charged to all students to help cover the cost of student health clinic operations and care delivery (separate from the purchase of student health insurance coverage by a subset of students) constitutes "cost-sharing," the imposition of which could violate the no cost-sharing requirements for certain preventive services. Such student health fees can be charged by the college or university to all students on a quarterly, semester or annual basis, regardless of whether a student utilizes a designated clinic or enrolls in student health insurance coverage. This type of student health fee is different from premiums and cost-sharing for group health plans and health insurance coverage in that it is charged to all students enrolled at the college or university, regardless of whether the student has student health insurance coverage. As a type of individual health insurance coverage, student health insurance coverage must comply with the requirements for preventive health services under section 2713 of the PHS Act, pertaining to the prohibition of cost-sharing for preventive services. However, because of the unique nature of the student health fee, the proposed rule would provide a definition of a student administrative health fee and clarify that such

fees are not cost-sharing requirements under PHS Act section 2713.

HHS is requesting comments on the applicability of section 2713 to student health insurance coverage and the interaction of the college health fee and the no cost-sharing requirement for preventive services.

4. Choice of Health Care Professional

Section 2719A of the PHS Act provides that if a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. Interim final regulations published on June 28, 2010 implemented rules for choice of health care professional (75 FR 37188). Concerns have been expressed by stakeholders representing colleges and universities that the provisions relating to choice of health care professional could be disruptive to the college health service system since it is a unique system which, although it is generally not indemnity coverage, is not structured like a traditional HMO or a PPO.

The proposed rule does not provide that the requirements of section 2719A would be inapplicable to student health insurance plans, but HHS is requesting comments on the applicability of the requirements for choice of health care professional to student health insurance coverage and the interaction with the college health service system.

5. Affordable Care Act Provisions Effective in 2014

HHS does not address in this proposed rule the applicability of PHS Act section 2702 (guaranteed issue) and section 2703 (guaranteed renewability) to student health insurance coverage, both of which are effective in the individual health insurance market for policy years beginning on or after January 1, 2014. HHS believes, however, that the general policy rationales supporting the inapplicability of PHS Act sections 2741 and 2742 to student health insurance coverage in this proposed regulation also would apply with respect to PHS Act sections 2702 and 2703. In addition, HHS could address in future regulations whether it would be appropriate to specify that these provisions would be inapplicable to student health insurance coverage provisions through the authority under section 1560(c) of the Affordable Care Act. Since student health insurance coverage is designed to be

available and renewable only to students of colleges and universities (and their dependents), it is likely that requiring student health insurance coverage to be available and renewable to individuals other than these students could prevent the design and development of student health insurance coverage.

HHS requests comments on the applicability of PHS Act sections 2702 and 2703 and other 2014 Affordable Care Act provisions to student health insurance coverage as defined in this proposed regulation. Comments are also requested on the interaction of student health insurance coverage with the health insurance Exchanges that will be created in States beginning in 2014.

6. Medical Loss Ratio (MLR)

Some issuers have raised concerns regarding the application of the medical loss ratio (MLR) provisions of section 2718 of the Affordable Care Act to student health insurance plans. This provision requires that, in general, at least 80% (in the small group and individual markets) or 85% (in the large group market) of the premiums that issuers receive for insurance policies be spent on reimbursement for clinical services to enrollees (such as hospital and physician payments) and activities that improve health care quality. The issuers assert that the

administrative cost structure of student health insurance plans is higher than the more typical individual policies, in part due to the customized nature of each college or university's plan, making compliance with the 80% MLR standard potentially prohibitive. For example, issuers stated that, compared to other health insurance coverage, student health insurance coverage may hold open enrollment periods more frequently (for example, each academic term rather than annually), require unique product designs (for example, for foreign students), and require more manual claims processing than average due to the billing and accounting practices of college health clinics. There is no public data regarding the actual expense structure of student health plans or regarding their MLRs.

HHS issued an interim final rule (IFR) (75 FR 74864, December 1, 2010, as modified by the Correction of IFR (75 FR 82277, December 30, 2010)), implementing section 2718, based on the recommendations in the MLR model regulation of the National Association of Insurance Commissioners (NAIC). In that regulation, issuers of policies that have a total annual limit of \$250,000 or less (so-called "mini-med" plans) and issuers of expatriate plans are required to report their mini-med and expatriate plan experience separately from their other policies for one-year, and, for

that one-year period, are provided an accommodation in the formula for determining the MLR for those lines of business. This was done because mini-med plans and expatriate plans were believed to have unique characteristics or expense structures and, as here, there is limited data regarding the administrative cost structures of these policies. This accommodation was made in order to allow the collection and analysis of data to determine if they have special circumstances that warrant special methodologies. The MLR IFR does not provide a special methodology for student health insurance plans.

To the extent that the application of the MLR requirements set forth in 45 CFR Part 158 to student health plans would "prohibit an institution of higher education . . . from offering a student health insurance plan," as section 1560(c) of the Affordable Care Act provides, then student health insurance plans may have unique administrative expenses that warrant developing methodologies that take such expenses into account in calculating the measure of activities to be reported as part of the MLR requirements. HHS is requesting comments on PHS Act section 2718 as it relates to student health insurance coverage.

E. Notice

1. Requirement

This proposed regulation would require a health insurance issuer to disclose to the student and any dependents in the insurance policy or certificate and any other written materials (for example, enrollment materials) that the policy being issued does not meet all of the requirements under the Affordable Care Act. HHS believes that the communication of this information is necessary in order for students and any dependents to understand the value and quality of the coverage that is being offered to them, and not have expectations that all of the requirements under the Affordable Care Act will apply. The notice would be required to provide a brief description of the requirements of the Affordable Care Act that do not apply to student health insurance coverage, and it would be required to be prominently displayed in clear, conspicuous 14-point bold type.

HHS is requesting comments on the notice requirement for student health insurance coverage.

2. Model Language

This proposed regulation would provide model language that can be used by health insurance issuers to satisfy the notice requirement. This proposed regulation would provide that substantially similar language can also be used to

satisfy the requirement. HHS is requesting comments on the model language.

F. Interaction with State Laws

As indicated earlier, many States do not regulate student health insurance as individual health insurance coverage but as a type of association blanket coverage or as non-employer group coverage. However, States have been aware, ever since the enactment of HIPAA in 1996, that health insurance coverage that is not sold in connection with employment is individual market coverage for purposes of the Federal statute (unless there is a specific exception such as for short-term limited duration insurance). The preemption provisions of section 2762 of the PHS Act (added by HIPAA and implemented in 45 CFR §148.210(b)) apply so that the PHS Act requirements are not to be "construed to prevent a State from establishing, implementing, or continuing in effect standards and requirements unless such standards and requirements prevent the application or requirement" of the PHS Act. The HIPAA conference report indicates that this is intended to be the "narrowest" preemption of State laws. (See House Conf. Rep. No. 104-736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018).

In applying this preemption standard, a State is free to continue to regulate student health insurance coverage as association coverage or as a form of group health insurance provided that doing so does not prevent the application of any of the applicable requirements and protections of the individual market provisions of the PHS Act and Affordable Care Act. If any State law or requirement prevents the application of a Federal standard, then that particular State law or requirement would be preempted. HHS invites comments on the interaction of specific State laws or requirements with the Federal standards regarding student health insurance coverage.

G. Conforming Amendments

Conforming amendments were made to the definitions in 45 CFR §144.103. First, this proposed regulation would clarify that the definitions apply to Part 147 unless otherwise noted. Second, a definition of student health insurance coverage is added, which cross references the definition of student health insurance coverage in 45 CFR §147.145(a).

H. Applicability Date

The applicability date of the proposed regulation would be for policy years beginning on or after January 1, 2012. This is because the Department recognizes that

health insurance issuers will need time to incorporate the requirements of individual health insurance coverage under the PHS Act that would apply to student health insurance coverage. HHS believes it would be appropriate to provide time for transitioning student health insurance coverage to comply with the PHS Act and Affordable Care Act to the extent necessary in order to maintain the offering of student health insurance coverage to students. To require that issuers of student health insurance coverage comply with the applicable provisions of the PHS Act and Affordable Care Act upon the effective date of the regulation would be disruptive to the student health insurance market.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. 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, summarized in Table 1. 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).

Proposed 45 CFR §147.145(d)(1) would require issuers of student health insurance coverage to provide notice to enrollees that the policy does not meet all of the requirements of the Affordable Care Act. In addition, the proposed regulation would require that the disclosure must be prominently displayed in clear, conspicuous 14-point bold type. Additionally, the proposed regulation provides model language that issuers of student health insurance

coverage can use in order to be in compliance with the notice requirement. The model language is provided in proposed 45 CFR §147.145(d)(2).

In order to provide the notices, the issuers of student health insurance coverage will need to review the model language or draft its own language, incorporate the plan or issuer's name into the model notice (or a notice that is similar to the model), and print the notice in any plan or policy documents that are regularly sent to student enrollees.

This burden estimate encompasses the entire notice process which includes assembly of the notice. It is estimated that approximately 75 student health insurance coverage issuers will have to provide such notice.¹² We estimate that it will take approximately 2 minutes per student enrollee or approximately 1,000 hours per student health insurance issuer to prepare and mail the notices to students. Including hourly wage and printing and mailing costs, we estimate the annual cost burden will be \$40,840 per affected issuer for a total cost of \$3,063,000. In some

¹² This estimate is based on data from the 2009 National Association of Insurance Commissioners (NAIC) Annual Accident and Health Policy Experience Exhibit and the American Council on Education (ACE). The 2009 NAIC filings show that there are 58 health insurance issuers offering student health coverage; however this data does not include managed care plans in California, and may include some issuers offering K-12 student accidental health coverage. In addition, data from the American Council on Education suggests that there are several smaller plans offering student health plans.

cases, actual burden per notice (for example, postage) may be lower because we expect that many issuers will insert the model language into the existing plan materials that they were already intending to send to enrollees each year.

Table 1: Annual Reporting, Recordkeeping and Disclosure Burden

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$)	Total Labor Cost of Reporting (\$)	Total Capital/Maintenance Costs (\$)	Total Cost (\$)
§147.145	0938-New	75	2,250,000	.0333	75,000	26.14	3,063,000	0	3,063,000
Total		75	2,250,000		75,000				3,063,000

If you comment on this information collection requirement, 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: CMS Desk Office, 9998-IFC. Fax: (202) 395-6974; or Email: 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 this preamble, this proposed regulation is designed to address several issues that have arisen regarding the applicability of the Affordable Care Act to student health insurance coverage, including how this coverage is categorized under the PHS Act. Specifically, the provisions in this proposed regulation clarify which protections of the PHS Act and the Affordable Care Act would apply to student health insurance coverage, and to what extent students and their dependents enrolled in these plans would have the benefit of these consumer protection provisions. This proposed rule would define student health insurance coverage as a type of individual health insurance coverage and specify certain PHS Act and Affordable Care Act requirements as inapplicable to this type of individual health insurance coverage. These provisions are generally effective for student health insurance policy years beginning on or after January 1, 2012.

The Department has proposed this regulation to implement the protections intended by Congress in the most

economically efficient manner possible. We have examined the effects of this rule as required by Executive Order 12866 (58 FR 51735, September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)). In accordance with OMB Circular A-4, the Department has quantified the benefits, costs and transfers where possible, and has also provided a qualitative discussion of some of the benefits, costs and transfers that may stem from this proposed regulation.

B. Executive Orders 13563 and 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). Executive Order 13563 (76 FR 3821, issued on January 21, 2011) is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866.

Section 3(f) of Executive Order 12866 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.

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, we have concluded that this proposed rule would likely not have economic impacts of \$100 million or more in any one year or otherwise meet the

definition of an "economically significant rule" under Executive Order 12866. Nevertheless, the Department has opted to provide an assessment of the potential costs, benefits, and transfers associated with this proposed regulation. This assessment is based primarily on the estimated administrative costs to issuers associated with providing the required notifications to student health plan enrollees. As discussed below, we believe that this proposed rule will have a minimal effect on premiums. The Department invites comments on this issue.

1. Need for Regulatory Action

In order to address several issues that have arisen regarding the applicability of the Affordable Care Act to student health insurance coverage, including how this coverage is categorized under the PHS Act, this proposed rule proposes that student health insurance coverage will be defined as a type of individual health insurance coverage and, with the exception of certain specific provisions, be subject to the individual market requirements of the PHS Act and the Affordable Care Act. As discussed elsewhere in the preamble, in clarifying the general applicability of the PHS Act and the Affordable Care Act to student health insurance coverage, this proposed regulation would also specify that a limited

number of requirements of the PHS Act and the Affordable Care Act are inapplicable to student health insurance coverage. Section 1560(c) of the Affordable Care Act provides that "[N]othing in this title (or an amendment made by this title) shall be construed to prohibit an institution of higher education (as such term is defined for purposes of the Higher Education Act of 1965) from offering a student health insurance plan, to the extent that such requirement is otherwise permitted under applicable Federal, State, or local law." The Department interprets this provision of the Affordable Care Act to mean that if particular requirements added by the Affordable Care Act would, as a practical matter, have the effect of prohibiting an institution of higher education from offering a student health plan otherwise permitted under Federal, State or local law, such requirements would be inapplicable pursuant to the rule of construction in section 1560(c). As discussed elsewhere in the preamble, based on factual information provided by stakeholders representing colleges and universities and students, the Department has determined that if insurance meeting the definition of student health insurance coverage were required to comply with all of the market reform provisions of the Affordable Care Act, this would be the functional

equivalent of "prohibiting" the educational institutions from making such coverage available to students. This proposed rule specifies that the requirements of the PHS Act relating to guaranteed availability and guaranteed renewability would be inapplicable to student health insurance coverage; would clarify that student administrative health fees are not cost-sharing requirements under section 2713 of the PHS Act; and would provide for a transition period for issuers of student health insurance coverage to comply with the restricted annual dollar limits requirements under the Affordable Care Act. The Department believes that the clarifications that are included in this proposed rule are necessary to facilitate the offering of student health insurance plans, consistent with the requirements of Section 1560(c) of the Affordable Care Act.

2. Summary of Impacts

In accordance with OMB Circular A-4, Table V.1 below depicts an accounting statement summarizing the Department's assessment of the benefits, costs, and transfers associated with this regulatory action. The Department has limited the period covered by the regulatory impact analysis (RIA) to 2012-2013. 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. Additionally, because this proposed regulation would clarify that student health insurance coverage is and has been subject to the provisions in the Affordable Care Act, including how these plans are categorized under the PHS Act, the RIA does not estimate the overall effect of imposing the Affordable Care Act provisions on these plans. Instead, the RIA focuses on the one proposed modification to the applicability of individual market requirements that would have a potential impact during the years 2011 - 2013. That is, providing for a transition period for issuers of student health insurance coverage to comply with the restricted annual dollar limits requirements of section 2711 of the PHS Act. This modification is designed to facilitate the offering of student health insurance plans, consistent with the requirements of section 1560(c) of the Affordable Care Act.

The Department anticipates that the provisions of this proposed rule will help institutions of higher education to maintain the offering of student health insurance coverage by clarifying the inapplicability of certain requirements of the PHS Act and Affordable Care Act that would prohibit the offering of such coverage. In accordance with

Executive Order 12866, the Department believes that the benefits of this regulatory action justify the costs.

Table V.1 - Accounting Table

Benefits:				
Qualitative: * Continued coverage, access to preventive services, and continuity of care for students. * Increased transparency relating to benefits offered in student health insurance coverage.				
Costs and Transfers:	Estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized (\$millions/year)	3.1	2011	7	2012-2013
	3.1	2011	3	2012-2013
Annual costs related to providing notifications to enrollees.				
Qualitative: * Reduced rate of premium growth for student health insurance coverage from 2011 through 2013 than would have occurred under immediate compliance with the restricted annual dollar limit requirements. * Increased out-of-pocket costs for a small number of enrollees.				

3. Estimated Number of Affected Entities

Comprehensive sources of data concerning the number of persons covered by student health insurance plans and the benefit structure of those plans are not readily available. Additionally, available survey data do not adequately capture this population due to small sample sizes and the difficulty of differentiating student health plans from other individual coverage. However, we were able to develop some estimates based on a Government Accountability Office (GAO) report and data provided by the American Council on Education (ACE).

a. Estimated Number of Plans Offering Student Health Insurance Coverage

There were 4,409 degree-granting institutions in 2009, including two-year and four-year institutions.¹³ The GAO found that 57 percent of colleges and universities offered student insurance plans in 2007-08,¹⁴ suggesting that approximately 2,500 colleges and universities offered such an insurance plan. According to industry sources, approximately 1,500 to 2,000 institutions offer student health plans, and the vast majority of these plans are insured (rather than self-insured) plans.¹⁵

In a survey of colleges with student health plans, GAO found that all but 4 percent established some maximum benefit amount during the 2007-08 academic year. Most (68 percent of plans) defined the maximum in terms of per condition per lifetime. Approximately 24 percent of the plans defined an annual limit (including plans with a per year or per-condition-per-year limit).¹⁶

¹³ U.S. Department of Education, National Center for Education Statistics. (2010). *Digest of Education Statistics, 2009 Table 265*.
http://nces.ed.gov/programs/digest/d09/tables/dt09_265.asp

¹⁴ Government Accountability Office, "Health Insurance: Most College Students Are Covered through Employer-Sponsored Plans, and Some Colleges and States Are Taking Steps to Increase Coverage," March 2008, GAO-08-389, p. 17.

¹⁵ It is estimated that approximately 200,000 students (less than 1% of the market) are enrolled in coverage offered through self-funded health plans. As discussed earlier in the preamble, these self-funded student plans are not subject to the requirements of the PHS Act because they are neither health insurance coverage nor group health plans, as those terms are defined in the PHS Act.

¹⁶ Government Accountability Office, March 2008, pp. 24, 27.

Additionally, as discussed earlier in the Collection of Information Requirements section, the Department estimates that there are approximately 75 health insurance issuers that offer student health insurance coverage that is provided to eligible students and their dependents through written agreements that are negotiated with the abovementioned colleges and universities that offer such coverage.

b. Estimated Number of Individuals Enrolled in Student Health Insurance Coverage

The GAO has estimated the percentage of college students aged 18 through 23 years old who are insured through nonemployer-sponsored private health insurance programs, including student health insurance programs. GAO found that 7 percent of college students aged 18 through 23 were covered by nonemployer-sponsored private health insurance programs, including student health insurance programs.¹⁷ However, almost one-half of all college students are not in this age group.

The National Center for Education statistics (NCES) has projected that there will be 19.0 million college students in 2012, approximately one-half of whom will be in

¹⁷ Government Accountability Office, March 2008, p. 10.

the 18-23 age range.¹⁸ Based on the previous GAO findings, a reasonable estimate of the total number of persons with student health insurance is approximately 1.3 million (approximately 7 percent of the estimated 19.0 million total college students). A separate source of information estimates that the five largest carriers offering student health insurance account for approximately 1.2 to 1.5 million enrollees; in addition, industry sources estimate that approximately 200,000 students are covered through student health plan arrangements that are self-funded through colleges and universities, and a relatively small number by insurers beyond the five largest carriers.¹⁹ By comparison, 2009 data from the National Association of Insurance Commissioners' (NAIC) Accident and Health (A&H) Policy Experience Exhibit suggest that health insurance issuers offered college student policies with approximately 1.1 million enrollees (based on estimated member years, including dependents).²⁰ There is clearly

¹⁸ U.S. Department of Education, National Center for Education Statistics. (2009), *Digest of Education Statistics, 2008, Table 190*. <http://nces.ed.gov/fastfacts/display.asp?id=98>

¹⁹ Based on information compiled by the American Council on Education, primarily from the American College Health Association and the health insurance industry, September 2010.

²⁰ This represents data for 32 health insurance issuers (e.g., licensed entities with unique NAIC company codes) that reported earned premiums and enrollment for student business in the individual or group markets on the NAIC Accident & Health (A&H) Policy Experience Exhibit for 2009, and excludes experience for companies regulated by the California Department of Managed Health Care. These issuers represent a subset of the 58 total issuers who reported any kind of student business on the NAIC A&H Policy Experience Exhibit for that year. The Department estimates that 16 issuers whose average premium per enrollee was approximately \$200 or less were primarily reporting data for K-12 student accidental health coverage, which is not subject to the provisions of this rule.

some uncertainty about the number of people enrolled in student health insurance coverage, but it appears likely that there are between 1.1 million and 1.5 million enrollees.

Table V.2 presents the estimated distribution of persons covered by student health insurance according to the annual limits of their policies, based on two different data sources. Regardless of which data source is used, the estimated number of students affected by this regulation is small. The first data source represents the distribution of annual limits in the individual market, as presented in Table 3.3 of the interim final regulation relating to section 2711 of the Affordable Care Act, regarding lifetime and annual dollar limits on benefits (75 FR 37188 (June 28, 2010)). Because that table did not use the annual limits thresholds relevant to this regulation, the estimated number of persons in each cell was prorated. Because the Affordable Care Act prohibits group health plans and health insurance issuers offering group or individual health insurance coverage from establishing lifetime limits on the dollar value of essential benefits, for purposes of this

The Department also excluded 10 issuers that did not report valid premium and/or enrollment data for student business from this analysis. In cases where data for member years were unavailable for certain issuers, the Department used data that were reported for covered lives or number of policies / certificates as a proxy.

analysis we assume that the plans with such limits (for example, 71.9 percent of the 199 plans in the GAO survey) have no annual limit. Another 4.0 percent of plans have had no limit of any type. Of the plans (13.6 percent) with per-condition-per-year limits, none had limits exceeding \$100,000. The distribution of the remaining 10.6 percent of plans was estimated based on three statistics reported in the GAO report.²¹

The second data source represents the findings from the 2008 GAO report. According to the GAO's analysis, only 24 percent of student health plans had an annual limit of any sort. Although the GAO found that most student health insurance coverage included other forms of maximum benefits during the 2007-2008 academic year (for example, per condition per lifetime), such limits are prohibited under current law and hence are not relevant to this analysis.

The GAO estimate suggests that approximately 300,000 students would potentially be affected by the proposal in this regulation to allow student health insurance coverage to have annual dollar limits lower than the \$750,000 that would be required in the absence of this rule.

²¹ These four percentages do not sum to 100 due to rounding.

Table V.2
Estimated Number of Persons with Student Health Insurance Coverage Subjected to Annual Limits, By Data Source

Annual Limit	HHS Estimated Distribution for All Plans Offered in the Individual Market		GAO Distribution For Student Health Plans With Annual Limits, 2007-2008	
	Percent	Number (in thousands)	Percent	Number (in thousands)
Less Than \$100,000	0.2%	3	21.6%	281
\$100,000 - \$749,999	2.2%	29	2.5%	33
\$750,000 - \$1,999,999	12.8%	166	0.0%	0
\$2,000,000 or Higher	84.8%	1,102	75.9%	986
Total	100.0%	1,300	100.0%	1,300

Note: The estimated number of persons in each cell has been prorated.

Sources: The HHS distribution was derived from HHS, 75 FR 37188, Table 3.3; the GAO distribution was derived from GAO, March 2008, GAO-08-389, pp. 24, 27.

Given that provisions of this proposed regulation would be applicable for policy years beginning on or after January 1, 2012, and assuming that most students enrolling in student health insurance coverage do so at the beginning of the fall semester, we believe that this proposed regulation is not likely to impact a significant number of students until late summer of 2012, at which point approximately 280,000 enrollees will see their annual limits increase to no less than \$100,000 on essential benefits (for student health insurance coverage policy years beginning on or after January 1, 2012, but before September 23, 2012), according to the GAO-based results.

Because this proposed regulation includes a phased transition to the restricted annual dollar limits

thresholds that are required under the Affordable Care Act, some students that would have otherwise experienced increases in their annual dollar limits for policy years beginning before September 23, 2012 under current law will not experience those increases. This includes an estimated 33,000 persons with coverage offering annual limits between \$100,000 and \$749,999. Additionally, in the late summer of 2013, an estimated 314,000 persons enrolled in coverage with annual dollar limits below \$2,000,000 will experience an increase in their annual dollar limits (to no less than \$2,000,000 for essential health benefits, consistent with the Affordable Care Act requirement for policy years beginning on or after September 23, 2012). Consistent with the provisions of the Affordable Care Act, no nongrandfathered student health insurance coverage will be allowed to have annual dollar limits for policy years beginning on or after January 1, 2014.

4. Anticipated Benefits, Costs and Transfers

As discussed earlier, because this proposed regulation is clarifying that student health insurance coverage policies are and have been subject to the provisions in the Affordable Care Act, the RIA does not estimate the overall effect of imposing the Affordable Care Act provisions on these plans. Therefore, the discussion of anticipated

benefits, costs and transfers focuses on the impacts associated with the clarification in this proposed rule that a limited number of requirements of the PHS Act and the Affordable Care Act are inapplicable to student health insurance coverage, in order to facilitate the offering of student health insurance plans, consistent with the requirements of section 1560(c) of the Affordable Care Act.

a. Benefits

The proposed regulation defines student health insurance coverage as a type of individual health insurance coverage and specifies certain PHS Act and Affordable Care Act requirements as inapplicable to this type of individual health insurance coverage. One such provision of this regulation is to provide for a transition period for issuers of student health insurance coverage to comply with the restricted annual dollar limits requirements under the Affordable Care Act. For example, student health insurance coverage will be allowed to impose an annual dollar limit of no less than \$100,000 on essential health benefits for policy years beginning on or after January 1, 2012, but prior to September 23, 2012. While we cannot quantify them at this time, we believe there would be economic benefits to this rule resulting from improved coverage and access to health services for students because in the absence of the

provisions in this proposed regulation, it is likely that there may have been some reductions in student health insurance availability - for example, due to the higher restricted annual dollar limits that otherwise would have applied in these years.

One rationale for the provision of a transition period for issuers of student health insurance coverage to comply with the restricted annual dollar limits requirements is that many student plans currently have annual limits substantially lower than the \$1.25 million requirement that will be in effect for plan years beginning on or after September 23, 2011. Concerns have been expressed that some institutions of higher education would not be able to offer student health insurance coverage if the annual dollar limits were immediately to increase by those amounts. While some students will have access to dependent coverage through their parents' health insurance plans up to age 26, this may not be an option for older students and students whose parents do not have coverage.²² In the absence of the provisions of this proposed rule, it is likely that some affected students would not be able to find affordable alternative coverage and become uninsured. To the extent

²² Andrews, Michelle, "Health-Care Overhaul Offers Insurance Benefits to Young Adults," *The Washington Post*, May 25, 2010, accessed at <http://www.washingtonpost.com/wp-dyn/content/article/2010/05/24/AR2010052403141.html>.

that the transition period for issuers of student health insurance coverage to comply with the annual dollar limits requirements results in these institutions of higher education continuing to offer coverage, there would be benefits in terms of maintaining student health. Students who would otherwise might have been uninsured will have continued coverage, access to preventive services and be able to continue care plans for acute and chronic illnesses.

Several other provisions in this proposed rule will also help colleges and universities to continue offering student health insurance coverage by maintaining current industry practices - including the clarifications relating to the inapplicability of the guaranteed availability and renewability requirements in the PHS Act before 2014 (in order to allow student health insurance coverage to be limited to eligible students and their dependents), and the clarification that student administrative health fees are not cost-sharing requirements under Section 2713 of the PHS Act. Additionally, the notice requirements in this proposed regulation will provide increased transparency relating to the benefits that are offered in student health insurance coverage. This will assist students in making the best selection among their available coverage options.

b. Costs and Transfers

In addition to maintaining coverage as described above, the transition period for issuers of student health insurance coverage to comply with the restricted annual dollar limits requirements will likely result in a somewhat reduced rate of premium growth for student health insurance coverage from 2011 through 2013 than would have occurred if the higher annual dollar limits were required for these years. As discussed earlier in the preamble, for plan years beginning after September 23, 2011, the minimum annual limit under the Affordable Care Act is \$1.25 million. This level is so much higher than many of the current annual dollar limits that if applied immediately to student health insurance coverage benefit designs, it could require large premium increases that would effectively "prohibit an institution of higher education... from offering a student health insurance plan."

At the same time, a small number of student enrollees are likely to face increased out-of-pocket costs than they would have faced if there were no transition period for issuers of student health insurance coverage to comply with the restricted annual dollar limits. Thus, there is a small transfer from this group which would have had higher

out-of-pocket costs to the population of students purchasing student plans through lower premiums.

There may also be some costs associated with the provisions in this proposed rule. Those adversely affected by the higher out-of-pocket costs may seek less care than they would have under higher annual dollar limits.

Finally, the Department estimates that there will be some administrative costs to issuers associated with the notice requirements. As discussed in the Collection of Information Requirements section, we estimate that approximately 75 student health plan health insurance issuers will have to provide notices to students and any dependents indicating that the coverage does not meet all of the requirements of the Affordable Care Act. We estimate that it will take approximately 2 minutes per student enrollee or approximately 1,000 hours per student health plan insurance issuer to prepare and mail the notices to student enrollees. Including hourly wage and printing and mailing costs, we estimate the annual cost burden will be \$40,840 per affected issuer, for a total cost of \$3,063,000. We believe that these cost estimates are conservative, as some issuers are likely to insert the model notice language into the existing plan documents that

they distribute to their enrollees, thus reducing their estimated costs.

C. Regulatory Alternatives

Under the Executive Order, HHS is required to consider alternatives to issuing regulations and alternative regulatory approaches. HHS considered the two regulatory alternatives below.

1. Require Student Health Insurance Coverage to be Offered through a Bona Fide Association

HHS considered requiring student health insurance coverage to meet the definition of a bona fide association, as that term is defined at 45 CFR §144.103, in order to be exempt from guaranteed availability and guaranteed renewability requirements under current law provisions before 2014. This approach would have required issuers of student health insurance coverage to comply with all of the individual market requirements of the PHS Act and the Affordable Care Act except for guaranteed availability and guaranteed renewability. However, the approach would have been cost-prohibitive on some institutions of higher education, causing them to drop coverage since student health insurance coverage today rarely is offered through associations (that is, student associations). In addition, associations affiliated with newly-established institutions

of higher education would have been unable to satisfy the requirement that a bona fide association be in existence for five years.

2. Change the definition of Short-Term Limited Duration Coverage

HHS also considered modifying the definition of short-term limited-duration insurance in 45 CFR §144.103 to make it more difficult for student health insurance coverage to qualify as such (for example, shorten the time limit from 12 months to 6 months). However, this change would have had broader implications for the health insurance market and not only for coverage offered by institutions of higher education because there are currently health insurance policies being offered in the general market that meet the current definition of short-term limited duration insurance. As indicated earlier, these products serve as stop-gap coverage for individuals who need health coverage for short periods of time. To change the definition of short-term limited duration insurance would have implications for this type of coverage.

HHS believes that the option adopted for this proposed rule (defining student health insurance coverage as individual health insurance coverage and limiting the applicability of the PHS Act and the Affordable Care Act

through its authority under Affordable Care Act section 1560(c)) strikes the best balance of extending certain protections of the Affordable Care Act to students and their dependents enrolled in the student health insurance plans while preserving the availability and affordability of such coverage.

D. 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).

As discussed in the Web Portal interim final rule (75 FR 24481), HHS 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 (currently \$7 million in annual receipts for health insurers, based on North American Industry Classification System Code 524114).²³

Additionally, as discussed in the Medical Loss Ratio interim final rule (75 FR 74918), the Department used a data set created from 2009 National Association of Insurance Commissioners (NAIC) Health and Life Blank annual

²³ 'Table of Size Standards Matched To North American Industry Classification System Codes,' effective November 5, 2010, U.S. Small Business Administration, available at <http://www.sba.gov>.

financial statement data to develop an updated estimate of the number of small entities that offer comprehensive major medical coverage in the individual and group markets. For purposes of that analysis, the Department used total Accident and Health (A&H) earned premiums as a proxy for annual receipts. The Department estimated that there were 28 small entities with less than \$7 million in A&H earned premiums offering individual or group comprehensive major medical coverage; however, this estimate may overstate the actual number of small health insurance issuers offering such coverage, since it does not include receipts from these companies' other lines of business.

As discussed earlier in this regulatory impact analysis, comprehensive sources of data concerning the student health insurance market are not readily available. However, for purposes of this regulatory flexibility analysis, the Department has used data for issuers who reported offering student coverage on the 2009 NAIC A&H Policy Experience exhibit as a proxy for estimating the potential number of small issuers that could be affected by the provisions in this proposed rule. Based on these data, the Department estimates that there are 4 small entities with less than \$7 million in A&H earned premiums that offer student health insurance coverage that is the subject of

this proposed regulation. These small entities account for 13 percent of the estimated 32 total issuers who reported offering such coverage.²⁴

The Department estimates that 100 percent of these small issuers are subsidiaries of larger carriers, and 100 percent also offer other types of A&H coverage. On average, the Department estimates that student health insurance coverage in the group market accounts for approximately 29 percent of total A&H earned premiums for these small issuers. Additionally, the Department estimates that the annual cost burden for these small entities relating to the notice requirements in this proposed rule will be \$40,840 per issuer (accounting for 2.3 percent of their total A&H earned premiums). As discussed earlier, the Department believes that these estimates overstate the number of small entities that will be affected by the requirements in this proposed regulation, as well as the relative impact of these requirements on these entities because the Department has based its analysis on issuers' total A&H earned premiums

²⁴ As discussed earlier in this regulatory impact analysis, these 32 health insurance issuers are licensed entities with unique NAIC company codes that reported earned premiums and enrollment for student business in the individual and group markets on the NAIC Accident & Health Policy Experience Exhibit in 2009, and exclude experience for companies regulated by the California Department of Managed Health Care. This represents a subset of the 58 total issuers who reported any kind of student business on the NAIC A&H Policy Experience Exhibit for that year (including some that the Department estimates are primarily offering K-12 student accident health coverage that is not subject to the provisions of this proposed regulation).

(rather than their total annual receipts). Therefore, the Secretary certifies that this proposed rule will not have a significant impact on a substantial number of small entities.

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.

E. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act (UMRA) 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 2011, that threshold level is approximately \$136 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 will be required to provide important Affordable Care Act and PHS Act protections for students enrolled in student health insurance coverage. Further, the estimated annual costs associated with the provisions of this proposed rule are approximately \$40,840 per affected entity (or approximately \$3,063,000 per year across all affected entities). Thus, this proposed regulation does not impose an unfunded mandate on State, local or tribal governments or the private sector. 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.

F. 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 the regulation of student health insurance coverage.

As discussed earlier in the preamble, some States do not regulate student health insurance as individual health insurance coverage, but rather as a type of association "blanket coverage" or as non-employer group coverage. Under this proposed regulation, student health insurance coverage will be defined as a type of individual health insurance coverage, and will therefore be subject to the individual market requirements of the PHS Act and the Affordable Care Act, with the exception of certain specific provisions that are identified in the proposed rule. States would continue to apply State law requirements

regarding student health insurance coverage. However, if any State law or requirement prevents the application of a Federal standard, then that particular State law or requirement would be preempted. Additionally, State requirements that are more stringent than the Federal requirements would be consistent with the requirements under this proposed rule. Accordingly, States have significant latitude to impose requirements with respect to student health insurance coverage 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 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 CMS Center for 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.

G. Congressional Review Act

This proposed regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to Congress and the Comptroller General for review.

List of Subjects

45 CFR Part 144

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

For the reasons stated in the preamble, the Department of Health and Human Services proposes to amend 45 CFR Chapter I as set forth below:

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

1. The authority citation for part 144 continues to read as follows:

Authority: Secs 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 USC 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

2. Section 144.103 is amended by--

a. Revising the introductory text.

b. Adding the definition of "Student Health Insurance Coverage" in alphabetical order.

The revisions and additions read as follows:

§144.103 Definitions.

For purposes of parts 146 (group market), 147 (health reform requirements for the group and individual markets), 148 (individual markets), and 150 (enforcement) of this subchapter, the following definitions apply unless otherwise provided:

* * * * *

Student Health Insurance Coverage has the meaning given the term in §147.145.

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP

AND INDIVIDUAL HEALTH INSURANCE MARKETS

3. The authority citation for part 147 continues to read as follows:

Authority: Secs 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 USC 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

4. A new §147.145 is added to Subchapter B to read as follows:

§147.145 Student Health Insurance Coverage.

(a) Definition. Student Health Insurance Coverage is a type of individual health insurance coverage (as defined in §144.103) that is provided pursuant to a written agreement between an institution of higher education (as defined in the Higher Education Act of 1965) and a health insurance issuer, and provided to students enrolled in that institution of higher education and their dependents, that meets the following conditions:

(1) Does not make health insurance coverage available other than in connection with enrollment as a student (or as a dependent of a student) in the institution of higher education.

(2) Does not condition eligibility for the health insurance coverage on any health status-related factor (as

defined in §146.121(a)) relating to a student (or a dependent of a student).

(3) Meets any additional requirement that may be imposed under State law.

(b) Exemptions from the Public Health Service Act.

(1) Guaranteed Availability and Guaranteed Renewability. For purposes of section 2741(e)(1) and 2742(b)(5) of the Public Health Service Act, Student Health Insurance Coverage as defined in paragraph (a) of this section is construed to be available only through a bona fide association.

(2) Annual Limits. (i) Notwithstanding the annual dollar limits requirements of §147.126, for policy years beginning before September 23, 2012, a health insurance issuer offering student health insurance coverage as defined in paragraph (a) of this section may not establish an annual dollar limit on essential health benefits that is lower than \$100,000.

(ii) For policy years beginning on or after September 23, 2012, a health insurance issuer offering student health insurance coverage must comply with the annual dollar limits requirements in §147.126.

(c) Student Administrative Health Fees. (1) Definition. A student administrative health fee is a fee

charged by the institution of higher education on a periodic basis to students of the institution of higher education to offset the cost of providing healthcare through health clinics regardless of whether the students utilize the health clinics or enroll in student health insurance coverage.

(2) Preventive Services. Notwithstanding the requirements under 2713 of the PHS Act and its implementing regulations, student administrative health fees as defined in paragraph (c)(1) of this section are not considered cost-sharing requirements with respect to specified recommended preventive services.

(d) Notice. (1) Requirements. (i) A health insurance issuer that provides student health insurance coverage must provide a notice informing students that the policy does not meet the requirements described in paragraph (b) of this section.

(ii) The notice must be prominently displayed in clear, conspicuous 14-point bold type on the front of the insurance policy or certificate and any other plan materials.

(2) Model language. The following model language, or substantially similar language, can be used to satisfy the notice requirement of this paragraph (d)(1): "Your student

health insurance coverage, offered by [name of health insurance issuer], may not meet the minimum standards required by title XXVII of the Public Health Service Act. Specifically, the coverage will not be renewed when you are no longer enrolled as a student at [name of institution of higher education]; and the restrictions on annual dollar limits on your benefits may not be the same as other types of coverage. For policy years beginning before September 23, 2012, if a policy for student health insurance coverage applies a dollar limit on the coverage it provides for key benefits in a year, that limit must be at least \$100,000. Your student health insurance coverage put an annual limit of: [dollar amount] on [which covered benefits - notice should describe all annual limits that apply]. If you have any questions or concerns about this notice, contact [provide contact information for the health insurance issuer]."

(e) Applicability. The provisions of this section apply for policy years beginning on or after January 1, 2012.

CMS-9981-P

Dated: February 2, 2011

Donald M. Berwick,

Administrator,

Centers for Medicare & Medicaid Services.

Approved: February 8, 2011

Kathleen Sebelius,

Secretary.

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