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Department of Health and Human Services

45 CFR Part 152

**Pre-Existing Condition Insurance Plan
Program; Interim Final Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 152

[OCIO-9995-IFC]

RIN 0991-AB71

Pre-Existing Condition Insurance Plan Program

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

ACTION: Interim final rule with comment period.

SUMMARY: Section 1101 of Title I of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) requires that the Secretary establish, either directly or through contracts with States or nonprofit private entities, a temporary high risk health insurance pool program to provide affordable health insurance coverage to uninsured individuals with pre-existing conditions. This program will continue until January 1, 2014, when Exchanges established under sections 1311 and 1321 of the Affordable Care Act will be available for individuals to obtain health insurance coverage. This interim final rule implements requirements in section 1101 of the Affordable Care Act. Key issues addressed in this interim final rule include administration of the program, eligibility and enrollment, benefits, premiums, funding, and appeals and oversight rules.

DATES: *Effective date:* This regulation is effective on July 30, 2010.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 28, 2010.

ADDRESSES: In commenting, please refer to file code OCIO-9995-IFC. 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-OCIO-IFC, 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: OCIO-9995-IFC, 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, SW., Washington, DC 20201

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

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

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 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: Ariel Novick, (301) 492-4290.

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

A. General

Historically, public policy has addressed the challenges of people with pre-existing conditions through either high risk pools or insurance reform. In general, high risk pools provide coverage of last resort for people who, because of their health, are denied coverage by private insurers or are unable to purchase coverage in the individual market except at substantially surcharged premiums due to their health status, and are ineligible for public coverage (such as Medicare or Medicaid). Most States that permit insurers to decline coverage for health reasons have established high risk pools as an alternative coverage option in their individual market. These current pools provide safety net coverage for people who have difficulty obtaining individual health insurance because of their pre-existing conditions. First established in 1976, 35 State high risk pools currently provide coverage to approximately 200,000 individuals, or about one percent of the individual market nationwide, and vary in terms of the populations they cover and the benefits they provide.

States and the Congress through the Affordable Care Act have also elected to use insurance reforms to address the accessibility and availability of health insurance coverage for high risk populations. Seven States have adopted guaranteed issue to ensure access to coverage, and two States prohibit health status from being a factor in setting premiums.¹ The Patient Protection and Affordable Care Act of 2010, (the Affordable Care Act or "the Act"), Public Law 111-148 applies a ban on pre-existing condition exclusions and "rate-ups" based on health status starting in

¹ Kaiser Family Foundation. *State Health Facts*. <http://www.statehealthfacts.org/>.

2014 and prohibits the use of pre-existing condition exclusions for children starting in plan or policy years that begin on or after September 23, 2010.² This temporary Federal program provides coverage to uninsured Americans with pre-existing conditions until the Affordable Care Act is fully implemented in 2014.

B. Overview: Section 1101 of the Patient Protection and Affordable Care Act

The Affordable Care Act, was enacted on March 23, 2010. The Health Care and Education Reconciliation Act (the Reconciliation Act), Public Law 111–152, was enacted on March 30, 2010. Section 1101 of the Affordable Care Act requires that the Secretary of the Department of Health and Human Services (HHS) establish, either directly or through contracts with States or nonprofit private entities, a temporary high risk health insurance program to provide access to coverage for uninsured Americans with pre-existing conditions. (Hereafter, we generally refer to this program as the Pre-Existing Condition Insurance Plan program, or PCIP program, to avoid confusion with the existing State high risk pool programs, which will continue to operate separately.)

The PCIP program is intended to remain in place from the time of its establishment until the Exchanges established under sections 1311 or 1321 of the Act go into effect on January 1, 2014. This interim final regulation sets policy only for this unique, temporary Federal program with fixed Federal funding. Presented below is a general overview of the statutory requirements for the new program. More detailed descriptions of the specific requirements are included below as part of the discussion of the associated regulatory provisions set forth in this interim final rule.

II. Provisions of the Interim Final Rule

A. General Provisions (Subpart A, § 152.1 Through § 152.2)

Section 152.1 of this interim final rule specifies the general statutory authority for the ensuing regulations and the scope of the program, consistent with section 1101 of the Act. Section 152.2 provides definitions for terms that appear throughout these regulations. Generally, the definitions are self-explanatory or taken directly from

section 1101 of the statute. The definitions set forth in subpart A apply to all of part 152 unless otherwise indicated and are applicable only for purposes of part 152.

The definition of “pre-existing condition exclusion” warrants a brief discussion. First, it is important to note that this definition applies only for purposes of the prohibition in section 1101(c)(2)(A) on a PCIP “impos[ing] any preexisting condition exclusion” under the coverage provided (an important protection for a program designed to offer coverage to those with a pre-existing condition), and is separate from the “guidelines” that determine pre-existing condition status under section 1101(d)(2)(3) for purposes of eligibility for enrollment in a PCIP. These latter eligibility provisions are set forth in subpart C of this rule, under section 152.14.

State laws vary with regard to the definition of a pre-existing condition exclusion. For purposes of defining a pre-existing condition exclusion, we adopted the definition of pre-existing condition currently used in the group market under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). We also took into account section 1201 of the Affordable Care Act, which prohibits denials of coverage because of a pre-existing condition. Thus, we specify that pre-existing condition exclusion has the same meaning as under 45 CFR 144.103. That is, the term refers to a denial of coverage, or limitation or exclusion of benefits, based on the fact that the individual denied coverage or benefits had a health condition that was present before the date of enrollment for the coverage (or a denial of enrollment), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that date. This would include exclusions stemming from a condition identified via a pre-enrollment questionnaire or physical examination, or the review of medical records during the pre-enrollment period.

B. PCIP Program Administration (Subpart B, § 152.6 and § 152.7)

As noted above, section 1101(b) of the Affordable Care Act provides that HHS may “carry out” the temporary high risk health insurance pool program either directly or through contracts with eligible entities, which are States and non-profit entities. Eligible entities must submit a proposal to carry out a PCIP in a time and manner, and containing such information, that the Secretary requires. Section 152.6 establishes the general rules for administration through either a

State or by HHS through a non-profit private entity. Section 152.7 then describes the proposal process and specifies that in order to contract with HHS, the eligible entity’s proposal must demonstrate capability to perform all functions necessary for the design and operation of a PCIP, and that its proposed PCIP is in full compliance with all of the requirements of this part.

These standards establish minimum requirements for PCIPs, and are supplemented by other requirements detailed in solicitation documents (such as the descriptions of the outreach plan and consumer information resources that each PCIP will establish) and incorporated into the final contracts with HHS.

B. Eligibility and Enrollment (Subpart C, § 152.14 Through § 152.15)

Section 1101(d) of the Affordable Care Act provides the basic eligibility criteria for the PCIP program, which are set forth under § 152.14. In addition, consistent with the Secretary’s general authority under section 1101(c)(2)(D) of the Act to establish requirements for a PCIP, we set forth enrollment and disenrollment requirements in § 152.15.

Eligibility for the PCIP Program (§ 152.14)

Under section 1101(d) of the Affordable Care Act and subparagraphs (1), (2) and (3) of § 152.14(a) of this interim final rule, an individual is eligible to enroll in a PCIP if he or she: (1) Is a citizen or national of the United States or is lawfully present in the United States as determined in accordance with section 1411 of the Affordable Care Act; (2) has not been covered under creditable coverage, as defined in section 2701(c)(1) of the Public Health Service Act as of the date of enactment, during the 6-month period prior to the date on which he or she is applying for coverage through the PCIP; and (3) has a pre-existing condition, as determined in a manner consistent with guidance issued by the Secretary. We further provide in § 152.14(a)(4) that an individual must be a resident of a State that falls within the service area of a PCIP.

Eligibility Conditioned on Citizenship and Immigration Status

Eligibility for the PCIP program is limited to citizens or nationals of the United States and individuals who are lawfully present in the United States. For the purpose of this regulation, lawfully present has the meaning presently used under the Children’s Health Insurance Program, provided in the State Health Official letter issued by

² These provisions do not apply to “grandfathered” plans. For a description of these provisions, see the interim final regulations implementing 2719A (regarding patient protections), published in the *Federal Register* on June 28, 2010 (75 FR 37188).

the Centers for Medicare and Medicaid Services (CMS) on July 1, 2010. Section 1101(d)(1) directs the Secretary to make a determination of citizenship and immigration status in accordance with section 1411 of the Act, which describes procedures to be employed for determining eligibility for the Exchanges and provides for these procedures also to be used in determining eligibility for the PCIP program. This section sets forth detailed requirements governing the type of information that applicants must provide and specific verification procedures that the Secretary of Health and Human Services, Commissioner of Social Security, and Secretary of Homeland Security would be required to follow to establish eligibility. Section 1411(c)(4) of the Affordable Care Act further provides that the Secretary shall conduct verifications and determinations “through the use of an on-line system or otherwise for the electronic submission of, and response to, the information submitted * * * with respect to an applicant,” or by “such other method as is approved by the Secretary” that determines “the consistency of the information submitted with the information maintained in the records of the Secretary of the Treasury, the Secretary of Homeland Security, and the Commissioner of Social Security”.

Under this authority, § 152.15(a)(3) specifies that a PCIP must verify that an individual is a United States citizen or national, or lawfully present in the United States. A PCIP can verify an individual’s citizenship or immigration status through the Social Security Administration or, if applicable, the Department of Homeland Security. In many cases, States may be able to automate verification of citizenship and immigration status by leveraging existing data exchanges that are currently in place for other programs, such as Medicaid and the Children’s Health Insurance Program. The Department of Homeland Security’s U.S. Citizenship and Immigration Services (USCIS) Systematic Alien Verification for Entitlements (SAVE) program provides online system to verify an individual’s immigration status. States can access this system after entering into the necessary Memorandum of Understanding with USCIS. An automated verification process will be used in all States where HHS is administering the PCIP program.

Some States are not able to have an automated “on-line system” or “electronic” process in place when they start accepting enrollments into their PCIPs. Therefore, these regulations

provide, as an “alternative method” approved by the Secretary, that a PCIP program may instead require the individual to provide documentation that establishes citizenship or immigration status. Subject to HHS approval, States using documentation procedures may switch to an automated system in the future. If a PCIP shares such information with the Social Security Administration or the Department of Homeland Security, consistent with the Privacy Act, the regulation specifies that a PCIP must include a disclosure that the information provided on the enrollment request may be shared with other government agencies for purposes of establishing eligibility. The type(s) of documentation PCIPs may use is subject to approval by HHS under the terms of the contract.

Eligibility Based on a 6-Month Period Without Insurance Coverage

Eligibility for the PCIP program is limited to individuals with no creditable coverage during the 6-month period prior to the date on which they apply for coverage through the PCIP. Section 2701(c)(1) of the Public Health Service Act on the date of enactment and 45 CFR § 146.113(a)(1) define creditable coverage as coverage of an individual under a group health plan, health insurance coverage as defined at 45 CFR 144.103, Medicare Part A or Part B, Medicaid, the Children’s Health Insurance Program, the TRICARE program, a medical care program of the Indian Health Service or of a tribal organization, a State health benefits risk pool (that is, existing State high risk pool), the Federal Employee Health Benefits program, a public health plan (for example, coverage through the Veterans Administration), or a health benefit plan offered under section 5(e) of the Peace Corps Act. Such creditable coverage includes health coverage provided to certain former employees, retirees, spouses, former spouses, and dependent children who are entitled to temporary continuation of health coverage at group rates under the Consolidated Omnibus Reconciliation Act of 1985 (COBRA). We specify under § 152.14(b)(3) that if an individual has already satisfied the requirement for a 6-month period without creditable coverage in connection with qualifying for a given PCIP under section 1101 of the Act, the individual will be considered to have satisfied this eligibility requirement for purposes of a PCIP in another State, if such individual moves to a different State and wishes to enroll in that State’s PCIP.

In light of the unique circumstances presented by infants who are less than six months old, the Department will issue guidance on how the requirement that the individual not have had creditable coverage during the six-month period prior to the application for the PCIP program applies to and can be satisfied by such infants. Factors to be considered in this guidance include whether coverage in the hospital under the mother’s plan at birth counts, current practices regarding insurers’ coverage of newborns, and the anti-dumping rules that direct the Secretary to prevent disenrollment of individuals from existing insurance due to their health status.

Eligibility Based on Having a Pre-Existing Condition

Under section 1101(d)(3), eligibility for the PCIP program is conditioned on individuals having a pre-existing condition, as “determined in a manner consistent with guidance issued by the Secretary.” We specify at § 152.14(c)(1) that a PCIP in a State, or the PCIP run by a non-profit in States that are not carrying out the PCIP program, may determine that an individual has a pre-existing condition, for purposes of PCIP eligibility, based on satisfying any one or more of the following criteria, subject to HHS approval: (1) The individual provides documented evidence that an insurer has refused, or has provided clear indication that it would refuse, to issue individual coverage on grounds related to the individual’s health; (2) the individual provides documented evidence that he or she has been offered individual coverage but only with a rider that excludes coverage of benefits associated with a pre-existing condition; (3) the individual provides documented evidence that he or she has a medical or health condition specified by the State and approved by the Secretary; or (4) other criteria as defined by the PCIP and approved by HHS.

We believe that these criteria are fully consistent with the intent of section 1101(d)(3) of the Act and address the problems that individuals with pre-existing conditions face when applying for insurance coverage in the individual market. That is, individuals with pre-existing conditions are often unable to obtain coverage for reasons that include an outright denial and an exclusion of coverage for the pre-existing condition. This includes instances when an individual applies for coverage and is informed by the carrier’s representative or Web site that they would be denied for coverage by the carrier due to the pre-existing condition. Providing States and non-profit entities operating a PCIP

the option of using these manifestations of having a pre-existing condition, rather than relying on a list of medical conditions, is consistent with the PCIP program goal of covering people who both have a pre-existing condition and otherwise cannot access insurance. We note that in some cases, individuals with pre-existing conditions are unable to obtain outright written coverage denials, but instead are told that carriers will not accept their applications. These regulations will permit PCIPs to exercise flexibility in determining exactly what type of communication constitutes a refusal to issue coverage.

Under § 152.14(c)(3), we specify that a PCIP may determine that an individual has a pre-existing condition based on evidence of the existence or history of certain medical or health conditions, as approved by the Secretary. This provision comports with our intention to permit the continuing use of eligibility standards that States use in their existing high risk pools, and permits a State that has guaranteed issue and community rated premiums to use an alternative test to showing a denial of coverage.

Finally, we provide at § 152.14(c)(4) that HHS may approve other criteria for meeting the definition of pre-existing condition under a given PCIP.

We anticipate that the first two criteria will be used in all States where individuals may be denied coverage or offered coverage with exclusionary riders. In the PCIP program serving States that have elected not to play a role in operating a PCIP program, only the first two criteria will be used, except with respect to individuals who are guaranteed to be issued a policy. PCIPs administered by States or non-profit entities may choose to utilize the additional criteria with HHS approval.

Eligibility for a PCIP Conditioned on Residing in the Plan's Service Area

Eligibility for a PCIP is limited to individuals who reside in the service area of the PCIP. At § 152.14(a)(4), we provide that an individual must be a resident of one of the 50 States or the District of Columbia which constitutes or is within the service area of the PCIP.

The statute explicitly acknowledges the role of a State (defined in section 1304(d) of the Act as the 50 States and the District of Columbia) with respect to the administration of PCIP, with no reference to "Territories" (see 1101(b)(2) and (3), 1101(e)(3), 1101(g)(3)(A) and (5)). Unlike section 1204(a) of the Health Care and Education Reconciliation Act of 2010, (which amended the Affordable Care Act and clearly specified a role for territories in the operation of

Exchanges), the Congress made no similar reference to Territories in connection with the PCIP program.

Enrollment and Disenrollment Process (§ 152.15)

Under our authority in section 1101(c)(2)(D) of the Act to impose "appropriate" requirements that PCIPs would be required to meet, § 152.15(a) and (b) require PCIPs to establish a process for enrolling and disenrolling individuals that is approved by HHS. Our intent is to permit the use of established enrollment policies and procedures in place under existing State high risk pools, to the extent that they are consistent with the statute.

Section 152.15(a)(2) of this interim final rule specifies that a PCIP must allow an individual to remain enrolled unless the individual is disenrolled under specified circumstances (for example, the individual moves out of the service area or obtains other creditable coverage) or the PCIP program is terminated. Our intent is to promote continuity of coverage for individuals who enroll in a PCIP until they are able to obtain coverage through the Exchange, under which participating insurers cannot exclude individuals with pre-existing conditions. We understand, however, that to the extent individuals can obtain other coverage, for example, by becoming entitled to Medicare or enrolling in employer-based health insurance, such coverage would obviate the need for coverage provided by the PCIP. Leveraging the availability of such coverage, by exiting the PCIP, enables other qualified individuals to enroll.

A PCIP is required to establish, consistent with § 152.15(b) of this interim final rule, a disenrollment process that is approved by HHS. As noted above, we seek to support States' ability to participate in this program by allowing them to adopt policies and procedures in use under existing high risk pool programs. We understand that current practice in State high risk pools is that an individual who does not pay his or her premiums on a timely basis may be disenrolled. We provide in § 152.15(b)(2) that, under these circumstances, the enrollee will receive sufficient notice and reasonable grace period for payment prior to any disenrollment taking effect not to exceed 61 days (the longest period currently provided for by States). The consequence of failing to pay premiums and any subsequent disenrollment is that an individual loses access to coverage and may not be able to re-enroll for 6 months. Thus, we believe that it is the PCIP's responsibility to

inform its enrollees prior to making a disenrollment effective. There are other circumstances in which involuntary disenrollment is appropriate and thus we establish at § 152.15(b)(3) that a PCIP must disenroll an individual in cases of death, where an individual obtains creditable coverage or no longer resides in the PCIP's service area, and other exceptional circumstances as established by HHS. We envision that such circumstances would include cases of fraud or intentional misrepresentation of material fact, and it is our intent to work with PCIPs to develop policies in these areas via sub-regulatory guidance. As we explain under our discussion of eligibility, an individual who is disenrolled because he or she no longer resides in the service area of a PCIP does not have to satisfy another 6-month continuous period without creditable coverage before applying to enroll in a PCIP in the new State of residence.

Section 152.15(c) requires that a PCIP establish rules governing effective dates of enrollments and disenrollments. In particular, a PCIP program must specify the deadline for receiving an enrollment application that would take effect on the first of the following month. In general, an individual who submits a complete enrollment request by an eligible individual by the 15th day of a month could access coverage by the 1st day of the following month. Exceptions to this policy will be subject to approval by HHS.

Finally, given the capped appropriation for this program, we recognize that PCIPs need sufficient programmatic flexibility to manage their costs and enrollment, to help ensure that the PCIP program's funding allocation is sufficient to cover claims and other program costs for the entire duration of the program. Thus, we establish authority under § 152.15(d) for a PCIP program to employ strategies to manage enrollment over the course of the program that may include enrollment capacity limits, phased-in (delayed) enrollment, premium and benefit adjustments that indirectly affect enrollment, and other measures, as defined by the PCIP and approved by HHS.

Benefits—(Subpart D, Sections 152.19 Through 152.22)

Covered Benefits (§ 152.19)

Required Benefits (§ 152.19(a))

The required benefit list in § 152.19(a) builds off of the essential health benefits under the new section 2707 of the Public Health Service Act, as enacted in the Affordable Care Act, for which

guidance has yet to be issued. The list is consistent with the most commonly covered services offered in existing State high risk pools, according to a survey conducted by the National Association of State Comprehensive Health Insurance Plans (NASCHIP) in 2009. Its benefits are also parallel to the benefits offered by the Federal Employees Health Benefits Plan (FEHBP).

Excluded Services (§ 152.19(b))

Section 152.19(b) sets forth a list of services that shall not be covered by any PCIP. While the specific benefits to be included and excluded by any PCIP are generally subject to HHS approval and review through the PCIP contracting process, this excluded services list addresses several areas where providing coverage is unequivocally prohibited. This list of excluded services parallels that of FEHBP.

The subject of Federal funding of abortion services with respect to the Affordable Care Act was addressed in the Executive Order issued by the President on March 24, 2010: The enactment of the Affordable Care Act left in place current restrictions that prohibit the use of Federal funds for abortion services, except in cases of rape or incest, or where the life of the woman would be endangered. Exec. Order No. 13,535, 75 FR 15,599 (Mar. 24, 2010). These restrictions currently apply to certain Federal programs that are similar to the PCIP program. The PCIP program is Federally-created, funded, and administered (whether directly or through contract); it is a temporary Federal insurance program in which the risk is borne by the Federal government up to a fixed appropriation. As such, the services covered by the PCIP program shall not include abortion services except in the case of rape or incest, or where the life of the woman would be endangered.

Pre-Existing Conditions Exclusions (§ 152.20)

Section 1101(c)(2)(A) of the Act requires that a PCIP established under this section not impose any pre-existing condition exclusions with respect to covered services. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) includes limitations for pre-existing conditions in the group market. This protection was expanded under section 1201 of the Affordable Care Act, which prohibits any pre-existing condition exclusions from being imposed by group health plans or group and individual health insurance coverage beginning January 1, 2014. The interim final rules issued pursuant to

section 2704 of the Public Health Service Act (as amended by the Affordable Care Act) under § 147 adopt, with minor modifications, the definition of pre-existing condition currently used under HIPAA.

Similarly, our rule prohibits PCIPs from applying any pre-existing condition exclusion to covered services, and consistent with the regulations implementing section 1201 of the Act, defines a pre-existing condition exclusion as a limitation or exclusion of benefits based on the fact that the condition was present before the date of enrollment in coverage (or a denial of enrollment), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that date.

Pursuant to the authority provided to the Secretary under section 1101(c)(2)(D), this interim final rule also prohibits PCIPs from imposing any type of coverage waiting period upon eligible individuals. For purposes of this rule, a waiting period is defined as the period immediately following the effective date of enrollment in which some or all benefits in the coverage are not provided. Accordingly, once an individual is enrolled in a PCIP consistent with the rules set forth in subpart C, full coverage must be provided to the individual starting with the effective date of enrollment.

Premiums and Cost-Sharing (§ 152.21) Standard Rate

Section 1101(c)(2)(C)(iii) of the Act requires that premium rates charged for coverage under the high risk pool program be established at “a standard rate for a standard population”. The National Association of Insurance Commissioners (NAIC) Model Health Plan for Uninsurable Individuals Act suggests that high risk pool plans “determine a standard risk rate by considering the premium rates charged by other insurers offering health insurance coverage to individuals.” Furthermore, section 2245(g)(2) of the Public Health Service Act (PHSA), which governs the existing Federal high risk pool grant program, defines the “standard risk rate” for the high risk pools to mean a rate that: (1) Is determined under the State high risk pool by considering the premium rates charged by other health insurers offering health insurance coverage to individuals in the insurance market served; (2) is established using reasonable actuarial techniques; and (3) reflects anticipated claims experience and expenses for the coverage involved.

In keeping with the methodology suggested by the NAIC Model Act and the Federal grant program, § 152.21 of this interim final rule generally interprets the phrase “standard rate for a standard population” to refer to the premium rates offered in the individual market in a given State. While existing State high risk pools’ premiums vary between 105–250 percent of the standard rate of the individual market, the Act requires that premiums in the PCIP program be at the standard rate, rather than a higher proportion of that rate. Therefore, this rule provides that a PCIP established under this section must not offer enrollees premiums at a rate that exceeds 100 percent of the standard individual market rate in the PCIP service area.

This interim final rule does not mandate a specific formula for calculating the standard rate. Instead, we specify that a PCIP may calculate the standard rate using reasonable actuarial techniques, as approved by the Secretary, that reflect anticipated experience and expenses. This requirement should accommodate reasonable variations in the methods that PCIPs may use to calculate a standard risk rate.

We also recognize that individual market rates in each State can vary as a consequence of individual State insurance laws. For example, some States require that insurers issue all applicants a policy or offer coverage at a community rate. In such situations, the standard individual rate may be considerably higher than in a State that permits insurers to reject applicants or set premiums on the basis of health status or other factors. To account for these variations, § 152.21(a) of these rules provides that, subject to approval by HHS, a PCIP may use other methods of determining the standard rate in the State. The exact methodology must be submitted and approved through the proposal process as specified in § 152.8 of this part.

Premium Variation

Section 1101(c)(2)(C)(ii) of the Act specifies that premium rates in a PCIP can vary on the basis of age by a factor not greater than 4 to 1. Section 2701(a)(3) of the PHSA as amended by the Affordable Care Act requires HHS, in consultation with NAIC, to define permissible age bands for rating purposes in the individual and group markets. However, the rating bands established under section 2701 will not be effective until January 1, 2014, and no such requirement exists for the PCIP program. Given these factors, this rule does not establish standard age bands

for the PCIP program beyond the statutory requirements. Thus, § 152.21(a)(2) of this rule simply follows the statutory requirement of section 1101(c)(2)(C)(ii) of the Act and provides that premiums charged in the PCIP can vary by age on a factor of not greater than 4 to 1. Specific age band rating will be established through the PCIP contracting process.

Section 1101(c)(2)(C)(i) of the Act requires that premiums in the PCIP program may vary only as provided under section 2701 of the PHSA, other than what is allowed in section 1101. Section 2701 permits premiums rates to vary in the individual and group markets by a finite number of factors. Gender rating, for example, is prohibited in the PCIP program.

Limits on Enrollee Costs

Section 1101(c)(2)(B) of the Act sets limits on enrollee costs in the PCIP program. Specifically, the issuer's share of the total allowed costs of benefits provided under such coverage cannot be less than 65 percent of such costs, subject to actuarial review and approval by the Secretary. Section 152.21(b)(1) of this rule provides that coverage under a plan offered by a PCIP must at a minimum meet this 65 percent threshold.

Section 1101(c)(2)(B)(ii) of the Act requires that coverage provided by PCIPs not have an out-of-pocket limit greater than the applicable amount described in section 223(c)(2) of the Internal Revenue Code, which sets the out-of-pocket limit for high deductible health plans associated with a tax favored health savings accounts. (This amount is \$5,950 for 2010.) Under § 152.2, we define out-of-pocket costs as the sum of the annual deductible and the other annual out-of-pocket expenses, other than for premiums, required to be paid under the plan. Section 152.21(b)(2) also notes that, consistent with IRS rules, the out-of-pocket limit may be applied only for in-network providers, consistent with the terms of PCIP plan benefit package.

Access to Services (§ 152.22)

As noted above, section 1101(c)(2)(D) of the Act provides that coverage offered via a PCIP must meet any other requirements determined appropriate by the Secretary of HHS. Section 152.22 provides that the PCIP may specify the network of providers from whom enrollees may obtain services, provided that the PCIP demonstrates to HHS that it has a sufficient number and range of providers to ensure that all covered services are reasonably available and accessible under such coverage. Section

152.22(b) makes clear that, in the case of emergency room services, such services must be covered out of network and out of area if (1) the enrollee had a reasonable concern that failure to obtain immediate treatment could present a serious risk to his or her life or health; and (2) the services were required to assess whether a condition requiring immediate treatment exists, or to provide such immediate treatment where warranted. We believe these requirements are in keeping with generally accepted standards with respect to the provision of emergency services in plans with network limits, such as those in place in the Medicare Advantage program under title XVIII of the Social Security Act and the commercial health insurance market.

E. Oversight (Subpart E, Sections 152.26 Through 152.28)

Appeals Procedures (§ 152.26)

Section 1101(f)(1) of the Act requires the establishment of an appeals process to enable individuals to appeal determinations under the PCIP program. We are interpreting this provision to apply both to determinations with respect to benefit coverage determinations and determinations with respect to an individual's eligibility for the program, including whether an individual is a citizen or national of the United States, or lawfully present in the United States.

Rather than establishing detailed, proscriptive requirements with respect to appeals procedures, § 152.26 of this interim final rule establishes minimum requirements that all PCIPs must meet. Section 152.26(b) specifies that a PCIP must provide for a timely redetermination of an eligibility or coverage determination; coverage determinations include both whether an item or service is covered and the amount paid by the PCIP. For coverage determinations, § 152.26(b)(3) further specifies that an enrollee has the right to a timely second-level appeal, or "reconsideration," by an independent entity.

The requirement for independent review of a plan's coverage redetermination ensures that the entity providing the reconsideration would have no stake of any kind in the outcome, and was not involved in the initial or reconsidered determination being reviewed. This requirement could be satisfied under a variety of arrangements, including (1) An existing appeal mechanism provided for under State law; (2) in the case of a State-administered PCIP, a review process created by the State; or (3) an

independent contractor, such as the independent review entities with which HHS contracts to review coverage determinations under the Medicare program.

These requirements are intended to permit States to use existing appeals or review mechanisms provided for under State law, and to permit other non-profit entities to utilize their existing internal appeals mechanisms. The actual appeals mechanisms will be subject to the Secretary's approval as part of the contracting process. Given both the temporary nature of the program and the statutory implementation timeframe for the new program, we believe that using these existing mechanisms is necessary and appropriate.

Fraud, Waste, and Abuse (§ 152.27)

Section 1101(f)(2) of the Affordable Care Act requires the Secretary to establish procedures to protect against fraud, waste, and abuse. To that end, § 152.27(a) of this interim final rule requires the PCIP to develop, implement, and execute operating procedures to prevent, detect, recover payments (when applicable or allowable), and promptly report to HHS incidences of waste, fraud, and abuse. These procedures are required to include identifying situations in which enrollees, potential enrollees, or their family members had access to employer-based coverage, and may have been discouraged from enrolling in that coverage. Should HHS become aware of instances involving fraud, waste, or abuse within the PCIP's operation, HHS will take appropriate action within the terms of the contract, or as otherwise provided by law. As stated in § 152.27(b), the PCIP shall cooperate with Federal law enforcement and oversight authorities in cases involving waste, fraud and abuse, and shall report cases in which an individual may have been discouraged from enrolling in other coverage to appropriate authorities. For example, if the coverage was an employer group health plan subject to ERISA, which prohibits discrimination based on health status, the matter should be reported to the Department of Labor for investigation and possible enforcement action.

Preventing Insurer Dumping (§ 152.28)

There is an incentive for employers and issuers to single out high risk and thus high-cost individuals and offer incentives for them to disenroll from their coverage and obtain coverage in PCIPs which offer such individuals guaranteed access to coverage without pre-existing condition exclusion at a standard premium, if they are uninsured

for at least six months. Congress recognized this potential issue and directed the Secretary under section 1101(e)(2) of the Act to establish criteria for determining whether health insurance issuers and employment-based health plans have discouraged individuals from remaining enrolled in prior coverage based on the health status of those individuals, and specifies certain criteria that shall be included in those established by the Secretary. Section 152.28 of this interim final rule thus sets forth these criteria, and requires that PCIPs establish procedures to identify and report to HHS instances where health insurance issuers or group health plans are discouraging high-risk individuals from remaining enrolled in their current coverage, in instances where such individuals subsequently are eligible to enroll in the PCIP.

Consistent with section 1101(e)(2) of the Affordable Care Act, section 152.28(c) of the interim final rule provides that if, in applying the criteria in section 152.28(b), it is determined that a dumping under section 152.28(a) has occurred, the Secretary may bill the issuer or group health plan for any medical expenses incurred by the PCIP for such enrollees. In these situations, the interim final rule also makes clear that the issuer or group health plan will be referred to appropriate Federal and State authorities for other enforcement action that may be warranted depending on the facts and circumstances. Finally, section 152.28(d) specifies that nothing in the subsection may be construed as constituting exclusive remedies for violations of the section or preventing States from applying or enforcing this section or other provisions of law with respect to health insurance issuers, consistent with section 1101(c)(3) of the Affordable Care Act. Additional guidance will be issued to prevent "dumping" from public programs like Medicaid and the Children's Health Insurance Program.

F. Funding (Subpart F, Sections 152.32 Through 152.35)

Use of Funds (§ 152.32)

Section 1101(g) of the Affordable Care Act appropriates \$5,000,000,000 to pay the claims and administrative costs of the PCIP program established under this section that are in excess of the amount of premiums collected from enrollees. Traditionally, in State high risk pools, as well as other insurance programs, the funds collected from enrollees as premiums and other funding streams are expended across two chief areas. The majority of funds collected as premiums are expended to pay the health expenses

for covered services incurred by enrollees. Administrative expenses, the costs of operating the program, make up the second major expense category. Section 152.32(a) of this interim final rule thus provides that all funds awarded under this program must be used exclusively to pay the allowable claims and administrative costs of a PCIP established under this section. Such costs include those incurred in the development and operation of the PCIP program, to the extent that those costs are in excess of the amounts or premiums collected from individuals enrolled in the program. PCIP program funds are not available for any other uses, such as to pay expenses or defray premiums of existing State high risk pools.

Although the Act does not specify the amount that a PCIP can spend on administrative expenses, § 152.32(b) of this rule permits PCIPs to spend no more than 10 percent of its total allotted funds towards administrative expenses. The 10 percent limitation is similar to what is imposed under the Children's Health Insurance Program (CHIP). Typical examples of the types of administrative costs and expenses that we expect to be incurred by PCIPs include: Start-up and program implementation activities, the production and distribution of information and outreach materials, eligibility determination and enrollment processing, claims processing, costs associated with prevention and detection of fraud, waste and abuse, and other ancillary services such as operation of a customer service call center, account maintenance, and appeals. We note that, given the start-up costs for the new PCIPs established under this program, and the need for expeditious implementation, this 10 percent cap applies to the total allotment for the duration of the program, as opposed to spending in a given year.

Initial Allocation of Funds (§ 152.33)

Section 1101(g) of the Act does not specify exactly how HHS should allocate funds for the purpose of this program. At the outset of the program, as specified under section 152.33, the Secretary has established initial allotment ceilings for PCIPs in each State using a methodology consistent with the funding allocation methodology used in CHIP, as set forth under 42 CFR Part 457, subpart F, Payment to States. (Note that, subject to these allocation ceilings, the estimated funding amounts available under the PCIP program contracts are established through the contracting process based

on the projected number of PCIP enrollees and their projected claims costs. Actual payments to PCIPs will be based on their reported cost statements during the life of the contract.)

Thus, the initial ceilings on PCIP funding allocations are based on a blended formula based on the State population, number of uninsured individuals under 65, and geographic health care costs. Under this formula, one half of the available funds are allocated based on the number of the nonelderly population in each State, compared to the total U.S. nonelderly population. This gives more populous States more funding and does not penalize those States that employ mechanisms to reduce the number of uninsured persons in their States.

The health care cost index that HHS will use to adjust the funding allocations will be based on the wages of employees in the health services industry, and is consistent with what we have used under the Children's Health Insurance Program. These wage data were developed by the Bureau of Labor Statistics of the Department of Labor through its Quarterly Census of Employment and Wages. This will include a weighted average of the wages in the health services industry represented by ambulatory health care services, hospitals, and nursing and residential care facilities. As in the CHIP formula, 15 percent of the cost factor is held constant, while 85 percent reflects how each State's average wage compares to the U.S. average. In order to insure that the geographic variation and cost adjustments accurately reflect statistics on population and the number of uninsured, the same year of data will be used to calculate population, number of uninsured, geographic health care costs, and cost adjustments.

Reallocation of Funds (§ 152.34)

As noted above, over time, spending under the PCIP program will be determined based on the actual enrollment and cost experience of the PCIPs across the country. Thus, we recognize that there may be a need to reallocate funds if actual experience indicates that, in a given State, not all of funds available under the allocation formula will be used. Section 152.34 accounts for this possibility by giving HHS explicit authority to reallocate funds among States if HHS determines that the PCIP in a given State will not make use of the total estimated funding originally allotted to that State. HHS will be receiving monthly reports on the program costs of each PCIP and will consult closely with PCIPs in evaluating these reports and making any decisions

with respect to the need for reallocations.

Insufficient Funds (§ 152.35)

Section 1101(g)(2) of the Affordable Care Act states that if HHS estimates for any fiscal year that the aggregate amounts available for the payment of the expenses of the high risk pool will be less than the actual amount of such expenses, HHS shall make such adjustments as are necessary to eliminate this deficit. Further, section 1101(g)(4) of this Act states that HHS has the authority to stop taking applications for participation in the program to comply with the funding limitations. Accordingly, § 152.35(c) of this rule provides that the PCIP, subject to HHS approval, may adjust premiums, alter required benefits, limit PCIP applications or take other measures to eliminate a projected deficit. Particularly in view of the capped appropriation for the PCIP program, HHS is committed to working very closely with the PCIPs to monitor PCIP enrollment and claims experience. To that end, the PCIP contracts include detailed reporting responsibilities with respect to PCIP enrollment and spending, as well as spelling out PCIP responsibilities for the development of mitigation strategies and recommended adjustments should the amounts available under a contract be less than the projected expenses. Lastly, § 152.35(d) ensures that, if the Secretary estimates that aggregate amounts available for PCIP expenses will be less than the actual amount of expenses, HHS reserves the right to make such adjustments as are necessary to eliminate such deficit, consistent with the terms of the PCIP contract.

G. Relationship to Existing Laws and Programs (Subpart G, § 152.39 Through § 152.40)

Relationship to Other Federal Health Insurance Regulation

We note that subtitles A and C of Title I of the Affordable Care Act contain new requirements that apply to group health plans and issuers of health insurance in the individual health insurance market which are governed by title XXVII of the PHSA. Some of these provisions address the same areas as the above provisions in section 1101 governing the PCIP program (e.g., premium amounts, beneficiary out-of-pocket expenses, and pre-existing conditions). These insurance reforms do not apply to the PCIP established under section 1101 of the Affordable Care Act and implemented in this interim final rule since the high risk pools do not meet the

definition of a group health plan or a health insurance issuer pursuant to sections 2791(a)(1) and 2791(b)(2) of the PHS Act.

Maintenance of Effort (§ 152.39)

Section 1101(b)(3) of the new law imposes a maintenance of effort requirement, which specifies that in order for a State to enter into a contract to administer a PCIP, a State must agree not to reduce the annual amount it expended on the operation of an existing State high risk pool in the year preceding the year in which a PCIP contract begins. We believe that the clear intent of this provision is to prohibit the shifting of costs of existing State high risk pools to the Federal government. The maintenance of effort requirement both ensures that the fixed \$5 billion in funding is used to meet the PCIP program goals and also reinforces the limitation of eligibility to individuals who are uninsured, as opposed to those already insured through a State high risk pool. At the same time, we recognize that States now use different sources of funds to support the operation of existing high risk pools. For example, many States rely upon assessments on the health insurance industry or health insurance providers to support their high risk pools, and States also commonly allow insurers to reduce premium tax payments by all or a percentage of such assessment.

Given the various funding models that are now in place in different States, we believe it is appropriate to permit States some latitude in terms of ways in which they can satisfy this requirement subject to Secretarial approval. Accordingly, section 152.39(a) specifies that in order for a State to enter into a contract with the Secretary it must comply with the maintenance of effort requirement set forth in section 1101(b)(3) of the Affordable Care Act in a manner approved by the Secretary. We anticipate that permissible methods of meeting this requirement would include, but are not limited to, maintaining either the total amount or the total per capita amount of State funding for the operation of an existing high risk pool (given that a State would be maintaining its effort per enrollee, and cannot control disenrollment), maintaining the same formula for providing funding for a State high risk pool, or establishing an altered formula that the Secretary determines will not reduce the total funds expended on the existing high risk pool. (Note that options such as the per capita approach would need to be evaluated in terms of other policies in effect in a State that could negatively influence enrollment

in an existing State high risk pool.) Again, all such approaches are subject to the approval of the Secretary.

Section 152.39(b) specifies that in situations where a State enters into a contract with HHS under this part, HHS shall take appropriate action, such as terminating the PCIP contract, against any State that fails to maintain funding levels for existing State high risk pools.

Relation to State Laws (§ 152.40)

Section 152.40 of this interim final rule reflects the provision in section 1101(g)(5) that specifies State standards that might otherwise apply to the coverage offered under a PCIP program are pre-empted, with the exception of laws relating to licensing or solvency. This language tracks similar language that applies to State regulation of health plans offering Medicare Advantage plans under Medicare Part C or drug coverage under Medicare Part D under title XVIII of the Social Security Act, and we would expect to interpret the language for purposes of the PCIP program in a manner similar to the way HHS has applied it under those programs.

H. Transition to Exchanges (Subpart H, § 152.44 Through § 152.45)

End of PCIP Coverage (§ 152.44)

Section of 152.44 of this interim final rule specifies that, consistent with section 1101(g)(3)(A) of the Affordable Care Act, enrollee coverage under the PCIP program will end effective January 1, 2014, because affordable coverage will be available under the Exchanges and insurance plans will no longer be permitted to exclude coverage for pre-existing conditions. Note that PCIP program contracts will remain in effect to provide for appropriate contractual close out periods, but coverage of claims under the PCIP program will extend only to the costs of covered services provided up through December 31, 2013.

Transition to the Exchanges (§ 145.45)

As provided by section 1101(g)(3)(B) of the Affordable Care Act, HHS will develop procedures to transition PCIP enrollees to the Exchanges (exchanges) that are established under sections 1311 or 1321 of the Act, in order to ensure there are no lapses in coverage for individuals enrolled in the PCIP program. Since these exchanges are still in the developmental stages, we believe it would be premature to specify transition procedures in this interim final rule. Thus, section 152.45 simply establishes that HHS will develop such transition procedures, and we encourage

comments on the best ways to carry out the transition.

III. 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.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking (NPRM) in the **Federal Register** and invite public comment on the proposed rule before publishing a final rule that responds to comments and sets forth final regulations that generally take effect sixty days later. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

The Affordable Care Act was enacted on March 23, 2010, and requires that a temporary high risk pool program be in place “not later than 90 days” after enactment. The publication of proposed regulations in an NPRM could not govern implementation of the high risk pool program, as they would constitute mere proposals with no force of law. The normal sixty-day public comment period provided for in the case of regulations proposed in an NPRM would by itself consume two-thirds of the time the statute provides for implementation. Under these circumstances, it would be impracticable and contrary to the public interest to delay putting regulations into effect that are necessary to implement the program until the rules have been subjected to prior notice and comment procedures.

Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 60-day public comment period. Also, because these regulations need to be in effect in order to undertake full implementation of the program, we also find good cause for waiving the normal delay in effective date that would apply, and these regulations are effective on July 30, 2010.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding Proposal Process (§ 152.7)

Section 152.7 states that a proposal from a State or from a nonprofit private entity shall demonstrate that the eligible entity has the capacity and technical capability to perform all functions necessary for the design and operation of a Pre-Existing Condition Insurance Plan (PCIP), and that its proposed PCIP is in full compliance with all of the requirements of this part. Specifically, the proposal shall demonstrate that the proposed PCIP satisfies at least the conditions listed at § 152.7(a)(1) through (9).

If there are States that do not submit acceptable proposals as described in § 152.7, HHS will solicit proposals from nonprofit entities to contract with HHS to operate a PCIP in those States. Nonprofits may submit proposals to contract directly with HHS to operate a PCIP program.

The burden associated with this requirement is the time and effort necessary for a State or nonprofit entity to develop and submit a proposal to operate a PCIP, which is a one-time information collection burden. We estimate that it would take a State or nonprofit entity 684 hours to compile the necessary information to comply with this requirement. While this one-time requirement is subject to the PRA, the associated burden is approved under OMB control number 0938–1085.

B. ICRs Regarding Eligibility (§ 152.14)

Section 152.14 discusses eligibility to enroll in a PCIP program. An individual who enrolls in a PCIP must meet both the requirements listed at § 152.14(a)(1), demonstrating they are a citizen or national of the United States or lawfully present in the United States and § 152.14(a)(3), providing evidence that they have a pre-existing condition as established under paragraph (c) of this section. The burden associated with this requirement includes the process of obtaining such information and forwarding the information to the appropriate party at the PCIP. We estimate this information could be submitted either electronically or hard copy in accordance with directions furnished by the PCIP and approved by HHS. We estimate that it will take approximately 30 minutes per applicant to obtain, review and submit the above proof(s) of eligibility. Although the Department has not estimated program participation, for the purpose of this calculation, we assume that within the first six months of the program approximately 100,000 potential enrollees will submit eligibility information to the PCIP program. The estimated one-time burden associated with this requirement is 50,000 hours. As the program progresses beyond 2010, we assume that we will receive fewer inquiries based on the experience with existing State high risk pool programs. In 2011 and beyond, we assume that approximately 50,000 potential enrollees will submit eligibility information to the PCIP program. The estimated annual burden associated with this requirement is 25,000 hours.

C. ICRs Regarding Enrollment and Disenrollment Process (§ 152.15)

Section 152.15(a) and (b) require a PCIP to develop and implement enrollment and disenrollment processes, respectively. The burden associated with these requirements is the time and effort necessary for a PCIP program to establish enrollment and disenrollment procedures. The burden associated with the establishment of enrollment and disenrollment procedures is a one-time burden that was included in the 684 burden hour estimate in our earlier discussion of § 152.7. While these requirements are subject to the PRA, the associated burden is approved under OMB control number 0938–1085.

In regards to ongoing reporting under the PCIP contract, any State or entity selected to administer the PCIP program may later decide it is in the best interest of their State to propose amendments to

the previously agreed upon contract. We estimate that, while uncommon, such instances may occur and permissible proposed changes would be allowed. When considering all aspects of the contract, which would include the enrollment and disenrollment process, access to services, and the appeals process, we estimate that it will take approximately 24 hours per contractor to submit a revised proposal and implement any approved amendments. The estimated annual burden associated with this requirement is 1,224 hours at a cost of \$28,152.

D. ICRs Regarding Access to Services (§ 152.22)

Section § 152.22(a) states that a PCIP may specify the networks of providers from whom enrollees may obtain plan services. The PCIP must demonstrate to HHS that it has a sufficient number and range of providers to ensure that all covered services are reasonably available and accessible to its enrollees. The burden associated with this requirement is the time and effort necessary for a PCIP to demonstrate to HHS that it has a sufficient number and range of providers to ensure that all covered services are reasonably available and accessible to its enrollees. The burden associated with these requirements is included in the 684 burden hour estimate for compiling the necessary information to comply with this requirement as stated in our earlier discussion of § 152.7.

In regards to ongoing reporting under the PCIP contract, any State or entity selected to administer the PCIP program may later decide it is in the best interest of their state to propose amendments to the previously agreed upon contract. We estimate that while uncommon, such instances may occur, and permissible proposed changes would be allowed. When considering all aspects of the contract, which would include access to covered services, we estimate that it will take approximately 24 hours per contractor to submit a revised proposal and implement any approved amendments. The estimated annual burden associated with this requirement is 1,224 hours at a cost of \$28,152.

E. ICRs Regarding Appeals Procedures (§ 152.26)

Section 152.26(a) requires a PCIP to establish and maintain procedures for individuals to appeal eligibility and coverage determinations. Section 152.26(b) lists the minimum requirements for appeals procedures. The burden associated with this requirement is the time and effort

necessary for a PCIP to develop and maintain appeals procedures. The burden associated with these requirements is included in the 684 burden hour estimate for compiling the necessary information to comply with this requirement as stated in our earlier discussion of § 152.7. The aforementioned information collection requirements and associated burden are currently approved under OMB control number 0938–1085.

In regards to ongoing reporting under the PCIP contract, any state or entity selected to administer the PCIP program may later decide it is in the best interest of their state to propose amendments to the previously agreed upon contract. We estimate that while uncommon, such instances may occur, and permissible proposed changes would be allowed. When considering all aspects of the contract, which would include the appeals process, we estimate that it will take approximately 24 hours per contractor to submit a revised proposal and implement any approved amendments. The estimated annual burden associated with this requirement is 1,224 hours at a cost of \$28,152.

F. ICRs Regarding Fraud, Waste, and Abuse (§ 152.27)

As stated in § 152.27(a), a PCIP shall develop, implement, and execute operating procedures to prevent, detect, recover (when applicable or allowable), and promptly report to HHS incidences of waste, fraud and abuse. Additionally, § 152.27(b) states that a PCIP program shall cooperate with Federal law enforcement authorities in cases involving waste, fraud, and abuse. The burden associated with the requirement contained in § 152.27 is the time and effort necessary to submit the required information on an ongoing basis. We estimate that it will take PCIPs 4 hours each month, per State, to report all required information to HHS and/or Federal law enforcement authorities which would include any identified instances of waste, fraud, and abuse. The estimated annual burden associated with this requirement is 2,448 hours at a cost of \$56,304.

G. ICRs Regarding Preventing Insurer Dumping (§ 152.28)

Section 152.28(b) requires a PCIP to establish procedures to identify and report to HHS instances in which health insurance issuers or group health plans are discouraging high-risk individuals from remaining enrolled in their current coverage and in instances in which such individuals subsequently are eligible to enroll in the qualified high risk pool.

The required procedures shall include methods to identify circumstances described in § 152.28(b)(1) through (4). The burden associated with this requirement is the time and effort necessary for a PCIP to establish procedures for identifying insurer dumping and for reporting dumping practices to HHS. We estimate that it will take PCIPs 8 hours each month, per State, to develop and report information to HHS of any health insurance issuer or group health plan they have identified as discouraging an individual from remaining enrolled in coverage offered by such issuer or health plan based on the individual's health status. The estimated annual burden associated with this requirement is 4,896 hours at a cost of \$110,160.

H. ICRs Regarding Use of Funds (§ 152.32)

Section 152.32 states that all funds awarded through the contracts established under this program must be used exclusively to pay allowable claims and administrative costs incurred in the development and operation of the PCIP that are in excess of the amounts of premiums collected from individuals enrolled in the program. The burden associated with this requirement is the time and effort necessary for a State to collect allowable cost information, review and submit such information to HHS for payment. We estimate that it will take each PCIPs 16 hours each month, per State to comply with this requirement. The estimated annual burden associated with this requirement is 9,792 hours at a cost of \$323,136.

I. ICRs Regarding Maintenance of Effort (§ 152.39)

Section 152.39(a) requires a State that enters into a contract with HHS under this part to demonstrate, subject to approval by HHS, that it will continue to provide funding of any existing high risk pools in the State at a level that is not reduced from the amount provided for in the year prior to the year in which the contract is entered. The burden associated with this requirement is the time and effort necessary for a State to demonstrate maintenance of effort to HHS. The burden associated with this one-time requirement is included in the 684 burden hour estimate for compiling the necessary information to comply with the proposal requirement as stated in our earlier discussion of § 152.7. While this requirement is subject to the PRA, the associated burden is approved under OMB control number 0938–1085.

TABLE 1—ANNUAL REPORTING AND RECORDKEEPING 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 (\$)
§ 152.7, § 152.15, § 152.22, § 152.26, § 152.39	0938–1085	51	51	684	34,884	**	1,421,268	0	1,421,268
§ 152.15, § 152.22, § 152.26	0938–1100	51	51	24	1,224	**	28,152	0	28,152
§ 152.14	0938–1095	100,000	100,000	.5	50,000	**	N/A	0	N/A
§ 152.27	0938–1100	51	612	4	2,448	**	56,304	0	56,304
§ 152.28	0938–1100	51	612	8	4,896	**	110,160	0	110,160
§ 152.32	0938–1100	51	612	16	9,792	**	323,136	0	323,136
Total	100,051	101,887	103,244	1,939,020

**Wage rates vary by level of staff involved in complying with information collection request (ICR). Wage rates are detailed in the Supporting Statement Part A for this (ICR). Wage rates vary from \$12 to \$60 hourly salary. Supporting Statement Part A for this (ICR).

We will accept comments for both the new information collection requirements contained in this interim final rule and the requirements previously approved under 0938–1085 and 0938–1095, respectively, for 60 days from the date of display for this interim final rule. At the conclusion of the 60-day comment period, we will publish an additional notice announcing the submission of the information collection request associated with this final rule for OMB approval. At that time, the public will have an additional 30 days to submit public comments to OMB for consideration.

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

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

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

Attention: CMS Desk Officer, [OCIO–9995–IFC]

Fax: (202) 395–6974; or

E-mail:

OIRA_submission@omb.eop.gov.

VI. Regulatory Impact Analysis

A. Summary and Need for Regulatory Action

Section 1101 of Title I of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), Public Law 111–148, requires that the Secretary establish, either directly or through contracts with States or nonprofit

private entities, a temporary high risk health insurance pool program to provide affordable health insurance coverage to uninsured individuals with pre-existing conditions. (We generally refer to this program as the Pre-Existing Condition Insurance Plan program, or PCIP program, to avoid confusion with the existing State high risk pool programs, which will continue to operate separately.) This program will continue until January 1, 2014, when Exchanges established under sections 1311 and 1321 of the Affordable Care Act will be available for individuals to obtain health insurance coverage without regard to their pre-existing condition. This interim final rule sets forth the initial regulations with respect to this new program, and is needed for its implementation. The rule addresses key issues regarding administration of the program, eligibility and enrollment, benefits, premiums, funding, appeals rules, and enforcement provisions related to anti-dumping and fraud waste and abuse.

Executive Order 12866 explicitly requires agencies to take account of “distributive impacts” and “equity.” Offering health coverage to uninsured Americans with pre-existing conditions at an affordable premium is needed to provide the opportunity for coverage to individuals that cannot otherwise obtain insurance in the market. It is a temporary program to provide a transition to the Affordable Care Act policies that take effect in 2014 that ban the use of pre-existing conditions in determining access, benefit and premiums. The \$5 billion in Federal funding appropriated for this program will yield a meaningful increase in

equity, and is a benefit of this interim final regulation.

B. Executive Order 12866

Under Executive Order 12866 (58 FR 51735), a “significant” regulatory action is subject to review by the Office of Management and Budget (OMB). Section 3(f) of the Executive Order defines a “significant regulatory action” as an action that is likely to result in a rule (1) having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. OMB has determined that this regulation is economically significant within the meaning of section 3(f)(1) of the Executive Order, because it is likely to have an annual effect on the economy of \$100 million in any one year. Accordingly, OMB has reviewed this rule pursuant to the Executive Order.

The Department provides an assessment of the potential costs, benefits, and transfers associated with these interim final regulations, summarized in the following table.

TABLE 1.1—ACCOUNTING TABLE

Benefits	
Qualitative: The Pre-existing Condition Insurance Plan will provide uninsured Americans with preexisting conditions that have been denied coverage or otherwise excluded from purchasing insurance coverage with an opportunity to obtain coverage. Providing this insurance option will increase access to health care and reduce financial strain for participants. It is also likely to improve health outcomes and worker productivity. Individuals who are especially vulnerable as a result of existing health problems and financial status may receive the greatest benefit from this program.	
Costs	\$1,939,020 annually for reporting and recordkeeping.
Qualitative: To the extent PCIP increases access to health care services, increased health care utilization and costs will result due to increased uptake. Administrative costs include: the cost of contractors to apply, the time cost for individuals to apply, and the contractors' costs of complying with program rules (e.g., conducting appeals, preventing fraud).	
Transfers	\$5,000,000,000 for the period from July 1, 2010 to December 31, 2013.
Qualitative: The \$5 billion in Federal funds is a transfer from the Secretary to contractors to aid in administering the program.	

a. Estimated Number of Affected Entities

This rule provides guidance for the States and nonprofit private entities that contract with HHS to establish PCIPs to provide affordable health insurance coverage to uninsured individuals with pre-existing conditions within each State. The States or nonprofit private entities that voluntarily participate in the PCIP program will be directly affected by this regulation as well as the terms of their contracts.

There are 35 State-based high risk pool programs today.³ First created in the 1970s, States adopted these programs to address insurance market failures for people with pre-existing conditions. The number of such existing State programs grew with the enactment of a Federal law, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), that requires States to provide either guaranteed issue policies in the individual market to a certain set of people who have been continuously covered or access to an acceptable alternative mechanism, such as a high risk pool. In addition, beginning in 2002, Federal grants provided seed money and a limited amount of loss subsidies for such programs. Ongoing financial support for State-based high risk pools varies, but is generally provided through assessments on issuers, enrollee premiums, State general revenue, and, recently, Federal grants. Each program also has different eligibility rules, benefits, premiums, and/or cost controls (e.g., pre-existing condition waiting lists, disease management). As of the end of 2008, there were approximately 200,000 enrollees in the 35 State high risk pools. The Government Accountability Office

³ U.S. Government Accountability Office, *Health Insurance: Enrollment, Benefits, Funding, and Other Characteristics of State High Risk Health Insurance Pools* (2009), <http://www.gao.gov/new.items/d09730r.pdf>.

(GAO) estimated that there were approximately 4 million uninsured people with health problems in States with high risk pools.⁴

The Affordable Care Act establishes a program that is similar in some respects to these programs, but has notable differences in terms of eligibility criteria, benefits, and premiums. These differences make it difficult to extrapolate potential enrollment in the PCIP program from the experience of existing State high risk pools.

First, none of the existing pools limit eligibility to people who have been uninsured for a minimum of six months whereas this is a pre-requisite for enrollment in the PCIP program. In general, the uninsured have different health problems, economic statuses, and demands for health care and health insurance than the insured population.⁵

Second, while the State programs and Federal program cover roughly the same benefit categories, the PCIP program bars both benefit carve-outs and waiting periods for pre-existing conditions, which 30 State programs employ.⁶ In addition, PCIP limits annual out-of-pocket spending to \$5,950 nationwide, whereas two State programs have no specified annual limits and six States have limits that exceed \$5,950 within each State's most popular high risk pool

⁴ U.S. Government Accountability Office, *Health Insurance: Enrollment, Benefits, Funding, and Other Characteristics of State High Risk Health Insurance Pools* (2009), <http://www.gao.gov/new.items/d09730r.pdf>. This estimate was based on the number of individuals with at least one chronic condition, from the 2006 Medical Expenditure Panel Survey (MEPS), applied to the Current Population Survey estimates of the population in States with high risk pools.

⁵ "The Uninsured: A Primer," *Kaiser Commission on Medicaid and the Uninsured* (2006), <http://www.kff.org/uninsured/upload/7451.pdf>.

⁶ Tanya Schwartz, "State High Risk Pools: An Overview," *Kaiser Commission on Medicaid and the Uninsured*. (2010), <http://www.kff.org/uninsured/8041.cfm>.

plan.⁷ These distinctions in benefits affect both the cost of health insurance per capita as well as the mix of enrollees. For example, a person with cancer may decide it is not worth the premiums to sign up for a State high risk pool that will not cover her chemotherapy in the first year of enrollment due to a waiting period. Immediate coverage of pre-existing conditions should increase demand in the new program relative to the existing pools, and may also lead to a somewhat less favorable mix of health risks, because people with problems requiring substantial medical care will receive more benefit from the new program than the existing pools.

Third, all State high risk pools set their premiums at a higher percent of the standard rate in the individual market than the PCIP program. In the existing pools, premiums average 140 percent of standard rate, and range from 105 percent to 250 percent of the standard rate or higher.⁸ The PCIP program's premiums are set at 100 percent of standard rate. PCIP's lower premium is expected to increase the number of people who will want to purchase coverage. One study estimated that lowering all State high risk pool premiums to 125 percent of the standard rate would increase enrollment by one-third.⁹ The lower premium may lead to a more favorable health mix of enrollees, because the higher premiums in existing pools make the pools less

⁷ U.S. Government Accountability Office, *Health Insurance: Enrollment, Benefits, Funding, and Other Characteristics of State High Risk Health Insurance Pools* (2009), <http://www.gao.gov/new.items/d09730r.pdf>.

⁸ National Association of State Comprehensive Health Insurance Plans. *Comprehensive Health Insurance for High-Risk Individuals: A State-by-State Analysis, 2009/2010*.

⁹ Austin Frakt, Steve Pizer, and Martin Wrobel, "Insuring the Uninsurable: The Growth in High-Risk Pools," *Abt Associates, HSRE Working Paper* (2002), <http://www.abtassociates.com/reports/HSRE-W12-highrisk.pdf>.

attractive to individuals with fewer health problems. Lower premiums may also attract individuals who are in poor health, but are unable to afford the premiums in the existing pools.

Fourth, fifteen States and the District of Columbia lack a high risk pool program today. These States do not have a high risk pool for a variety of reasons. Some States, such as New York, Massachusetts, and Vermont, have enacted insurance reforms that require plans to accept people with pre-existing conditions into the individual insurance market (through guaranteed issue and rating rules) instead of segregating them into high risk pools. Others, like Arizona and Nevada, do not have extensive insurance reforms. There is no common profile to States that lack high risk pools today.

Lastly, there is no clear correlation between high risk pool enrollment and need. One measure of need is the number and rate of uninsured residents. A State that provides protections for its residents with high risk or low income should have a relatively low number and rate of uninsured residents, and vice versa. As such, among States that offer such pools, there should be a relatively constant relationship between a State's number of uninsured and its enrollees in high risk pools. However, experience suggests otherwise. The difference between the highest and lowest ratio of a State's uninsured population to its high risk pool enrollees is 27 to one. This is substantially larger than the disparity in the ratio of uninsured to Medicaid enrollees in a State, which is six to one.¹⁰ A report that examined current State high risk pools, estimated a participation rate of 0.05 to 0.33 percent of the State population in those programs.¹¹ For these reasons, the Department concludes that the experience in existing high risk pools is not a good basis for estimating PCIP enrollment.

Several reports have estimated the likely number of enrollees in the PCIP program by using survey data and applying a participation rate to the approximate number of people eligible for the PCIP program. One analysis was conducted by the Center for Studying Health System Change.¹² Using the Medical Expenditure Panel Survey

(MEPS), the analysis identified individuals who were uninsured and had at least one chronic condition deemed "high cost," meaning spending exceeds 1.5 times of the average cost of the condition. This methodology generated 5.6 to 7 million people who could potentially qualify for the program. Assuming that the annual Federal cost per person is \$6,000 to \$7,000 and the \$5 billion in Federal funding is capped in each year over the three and a half year period (roughly \$1.3 to \$1.4 billion per year), the analysis estimated that 200,000 people per year through 2013 could be covered.

Second, the Centers for Medicare and Medicaid Services' Office of the Actuary (OAct) estimated participation based on demand, without assuming that Federal funding would be limited to \$1.3 to \$1.4 billion in each year. It estimated that participation in the program in 2010 would be 375,000, assuming the program would be fully implemented within the year. Given this enrollment rate, it projected that the \$5 billion in Federal funding would not last through 2013.

Third, the Congressional Budget Office (CBO) conducted two analyses. In a December 2008 report, CBO estimated the cost and coverage of a national high risk pool program. This program would require that all States establish high risk pool programs, with full Federal subsidies for enrollees. Its premiums would be higher than PCIP—150 versus 100 percent of the standard rate—but its enrollment would be broader—significantly, it would not require that applicants have been uninsured for the previous six months. CBO estimated that 175,000 uninsured would gain coverage in this program, and the Federal cost would be \$5.4 billion over five years (with offsetting receipts from changes in employer coverage).¹³

In addition, in June, 2010, CBO provided information on PCIP in response to a request from Congress.¹⁴ Its methodology was not explained in its letter, but it calculated that 200,000 people could be enrolled in the program for the 2010–2013 period given the fixed \$5 billion appropriation. If the Federal funding cap were lifted, CBO estimated that enrollment would be 400,000 in 2011 rising to about 600,000 or 700,000 in 2013. CBO underscored the uncertainty of the estimates due to the potential variation in eligibility rules, benefits, and premiums. Since this

interim final rule preserves variation and flexibility in program parameters across States, CBO's observations continue to be relevant and there may be a wide range of potential enrollees. CBO would probably continue to estimate a wide range of potential enrollees taking this interim final rule into account.

For purpose of this analysis, the Department has not produced its own estimates of the number of individuals likely to enroll in the PCIP program but believes that it will fall in the range of the other estimates, from 200,000 to 400,000. The lower bound of this range is consistent with the numbers estimated by the Center for Studying Health System Change and by CBO in June 2010. The upper bound of this range is approximately the enrollment estimate from the Office of the Actuary and CBO when they assume that PCIPs do not immediately impose enrollment constraints to extend the limited Federal funding. We expect that efficient program implementation, effective cost control, targeted benefit design, and enrollment patterns that are different than projected will mitigate the need for enrollment constraints, and Federal funding will be sufficient to meet program demand. Even assuming the lower estimate of enrollment of 200,000, the PCIP program could double the number of Americans with pre-existing conditions insured through high risk pool programs.

c. Benefits

A key premise for the establishment of the Pre-Existing Condition Insurance Plan is that those who are unable to purchase health insurance in the private sector due to medical underwriting and are not eligible for public insurance programs are potentially disadvantaged through both poor health and loss of income. We expect that the PCIP program will help such individuals by providing access to affordable health insurance coverage.

This interim final regulation could generate significant benefits to consumers. These benefits could take the form of reductions in mortality and morbidity, reductions in medical expenditure risk, increases in worker productivity, and decreases in the cross-subsidy in premiums to offset uncompensated care, sometimes referred to as the "hidden tax." Each of these effects is described below.

A first type of benefit is reductions in mortality and morbidity. While the empirical literature leaves many questions unresolved, a growing body of evidence convincingly demonstrates that health can be improved by

¹⁰ Data from State Health Facts.org, Kaiser Family Foundation.

¹¹ "State High Risk Pools: An Overview." *State Health Access Data Assistance Center* (2008).

¹² Mark Merlis, "Health Coverage for the High-Risk Uninsured: Policy Options for Design of the Temporary High-Risk Pool," *National Institute for Health Care Reform, Center for Studying Health System Change* (2010).

¹³ Congressional Budget Office. *Health Care Budget Options Volume I*. December 2008.

¹⁴ Congressional Budget Office Director Douglas W. Elmendorf, letter to Senator Michael B. Enzi, June 21, 2010.

spending more on at-risk individuals and by expanding health insurance coverage. For example, Almond *et al.*¹⁵ find that newborns classified just below a medical threshold for “very low birthweight” have lower mortality rates than newborns classified as just above the threshold, despite an association between low birth weight and higher mortality in general, because they tend to receive timely and appropriate medical care. In a study of severe automobile accidents, Doyle¹⁶ found that uninsured individuals receive less care and have a substantially higher mortality rate. Currie and Gruber¹⁷ found that increased eligibility for Medicaid coverage expanded utilization of care for otherwise uninsured children, leading to a sizeable and significant reduction in child mortality. A study of Medicare by Card *et al.*¹⁸ found that individuals just old enough to qualify for coverage have lower mortality rates—despite similar illness severity—than do those just too young for eligibility. Finally, a report by the Institute of Medicine (IOM)¹⁹ found mortality risks for uninsured individuals that were 25 percent higher than those of observably similar insured individuals. In addition to the prospect that expanded insurance coverage will result in reductions in mortality, it will almost certainly significantly reduce morbidity, as demonstrated in extensive reviews of the literature by Hadley and the IOM.²⁰

This interim final regulation will expand access to currently uninsured individuals with pre-existing conditions. These newly insured populations will likely achieve both mortality and morbidity reductions from the regulation greater than those found

in the studies, since these populations are, on average, in worse health than the population at large and thus likely to benefit even more from insurance coverage than uninsured individuals in general.

A second type of benefit from the cumulative effects of this interim final regulation is a reduction in financial burden faced by the uninsured on account of onerous medical costs. Various studies have documented two related phenomena: (1) Averted healthcare utilization among the uninsured due to cost and (2) financial strain due to medical expenditures among the uninsured. Recent data show that 24 percent of the uninsured went without needed health care due to cost compared to 4 percent of those with private or employer-based insurance.²¹ Given the population targeted by the PCIP program—uninsured people with pre-existing conditions—individuals currently without insurance may not be able to simply forgo needed care, leading to substantial financial strain. Approximately half of the more than 500,000 personal bankruptcies in the U.S. in 2007 were in part due to very high medical expenses.²² In a Commonwealth Fund report²³ on medical debt, 60 percent of those having no insurance reported having difficulties paying medical care costs. In the past 12 months, they had incurred medical bills they either could not pay, were forced to make significant changes in their life styles in order to meet their obligations, had been contacted by a bill collection agency, or were forced to pay medical bills over an extended period. Exclusions from health insurance coverage based on preexisting conditions expose the uninsured to the aforementioned financial risks.

The Pre-Existing Condition Insurance Plan is designed to reduce the uncertainty and hardship associated with these financial risks by limiting the extent to which individuals must bear the entire cost of medical care by themselves. One study found that people who are uninsured for a full year pay for over a third of their care (35 percent) out-of-pocket, while individuals who are insured for a full or partial year paid just under 20 percent

of their care out-of-pocket.²⁴ Moreover, because the PCIP program is targeted to individuals who are likely to have extensive medical needs, it is likely to have especially large economic benefits in terms of reducing financial risk. For example, uninsured individuals with two chronic conditions spent \$908 out of pocket annually compared to \$304 annually among the uninsured with no chronic conditions and \$259 annually among the privately insured with no chronic conditions.²⁵ This program and the interim final regulation that implements it will help insurance companies more effectively protect patients from the financial hardship of illness, including bankruptcy and reduced funds for non-medical purposes.

A third type of benefit from the PCIP program and this interim final regulation is improved workplace productivity. This interim final regulation will benefit employers and workers by increasing workplace productivity and reducing absenteeism, low productivity at work due to preventable illness, and “job-lock.” A June 2009 report by the Council of Economic Advisers found that increased access to health insurance coverage improves labor market outcomes by improving worker health.²⁶ The health benefits of offering health insurance to uninsured people with pre-existing conditions will help to reduce disability, low productivity at work due to preventable illness, and absenteeism in the work place, thereby increasing workplace productivity and labor supply. Economic theory suggests that these benefits would likely be shared by workers, employers, and consumers.

Fourth, the PCIP will reduce cost shifting of uncompensated care to the privately insured, which contributes to higher premiums. The program will help expand the number of individuals who are insured and reduce the likelihood that individuals who have insurance do not bankrupt themselves by paying medical bills. Both effects will help reduce the amount of uncompensated care that imposes a “hidden tax” on consumers of health care since the costs of this care are

¹⁵ Douglas Almond *et al.*, “Estimating Marginal Returns to Medical Care: Evidence from At-Risk Newborns,” *The Quarterly Journal of Economics* 125, No. 2 (2010): 591–634, <http://www.mit.edu/~jdoyle/vlbw.pdf>.

¹⁶ Joseph J. Doyle, “Health Insurance, Treatment and Outcomes: Using Auto Accidents as Health Shocks,” *The Review of Economics and Statistics* 87, No. 2 (2005): 256–270, <http://www.mitpressjournals.org/doi/abs/10.1162/0034653053970348>.

¹⁷ Janet Currie and J. Gruber, “Health Insurance Eligibility, Utilization of Medical Care, and Child Health,” *The Quarterly Journal of Economics* 111, No. 2 (1996): 431–466, <http://www.jstor.org/stable/2946684?cookieSet=1>.

¹⁸ David Card, C. Dobkin, and N. Maestas, “Does Medicare Save Lives?” *The Quarterly Journal of Economics* 124, No. 2 (2009): 597–636, <http://www.mitpressjournals.org/doi/abs/10.1162/qjec.2009.124.2.597>.

¹⁹ Institute of Medicine, “Care Without Coverage: Too Little, Too Late,” (2002), http://books.nap.edu/openbook.php?record_id=10367&page=R1.

²⁰ Institute of Medicine, op. cit. J. Hadley, “Sicker and Poorer: The Consequences of Being Uninsured,” *Medical Care Research and Review* 60 (No. 2): 3S–75S, (2003).

²¹ Kaiser Family Foundation, “The Uninsured A Primer,” (2009), <http://www.kff.org/uninsured/upload/7451-05.pdf>.

²² David Himmelstein *et al.*, “Medical Bankruptcy in the United States, 2007: Results of a National Study,” *The American Journal of Medicine* (2009), http://www.pnhp.org/new_bankruptcy_study/Bankruptcy-2009.pdf.

²³ Collins *et al.*, “The Affordability Crisis In U.S. Health Care: Findings From The Commonwealth Fund Biennial Health Insurance Survey,” (2004): 17.

²⁴ Jack Hadley and John Holohan, “The Cost of Care for the Uninsured,” *The Kaiser Commission on Medicaid and the Uninsured* (2004), <http://www.kff.org/uninsured/upload/The-Cost-of-Care-for-the-Uninsured-What-Do-We-Spend-Who-Pays-and-What-Would-Full-Coverage-Add-to-Medical-Spending.pdf>.

²⁵ Hwang *et al.*, “Out of Pocket Medical Spending for Care of Chronic Conditions,” *Health Affairs* (2001), <http://www.partnershipforsolutions.org/DMS/files/Out-of-pocket2002.pdf>.

²⁶ Council of Economic Advisers. “The Economic Case for Health Reform.” (2009).

shifted to those who are able to pay for services in the form of higher prices.

In their analysis of the interim final regulations implementing patient protections, the Departments of Labor, the Treasury, and Health and Human Services estimated an order of magnitude for the compensatory reduction in cost-shifting of uncompensated care associated with the expansion of coverage of those interim final regulations.²⁷ The analysis assumed that induced utilization due to expanded coverage would be relatively low since the uninsured populations affected by these interim final regulations tend to have worse health, greater needs for health care, and less ability to reduce utilization when they are uninsured. Second, on the basis of the economics literature on the subject,²⁸ the Departments estimated that two-thirds of the previously uncovered costs would have been uncompensated care, 25 percent of which would have been paid for by private sources. Assuming that reductions in privately-financed uncompensated care lower insurance premiums charged to consumers, the Departments estimated the patient protections' regulations' increased insurance coverage could result in reductions in insurance premiums of up to \$1 billion in 2013.²⁹

Assuming an enrollment range of 200,000 to 400,000 in the PCIP program, the effect on uncompensated care could be over twice to four times as high as prior estimates associated with the patient protections. This increased impact is due to the fact that the primary effect on coverage of the patient protections interim final regulations was the ban on pre-existing condition exclusions for children. Those rules

²⁷ *Federal Register* June 28, 2010: <http://fwebgate1.access.gpo.gov/cgi-bin/TEXTgate.cgi?WAISdocID=3HyQc/5/1/0&WASAction=retrieve>.

²⁸ Jack Hadley *et al.*, "Covering the Uninsured in 2008: Current Costs, Sources of Payment, and Incremental Costs," *Health Affairs* 27, No. 5 (2008): 399–415.

²⁹ The Departments first estimated the proportion of the population in group and individual markets using the Medical Expenditure Panel Survey (2008). Next, information from 75 FR 34538 (June 17, 2010) was used to estimate the proportion of employer and individual plans that maintain or lose grandfather status by 2013. Projections of national health expenditures from the National Health Expenditure Accounts to 2013 were distributed among these groups, and premium impacts as discussed in this regulatory impact analysis were applied. Potential premium reductions secondary to reductions in the cost-shifting of uncompensated care were then calculated using the information from the economic literature as presented in this discussion. The Departments note that to the extent that not all of the reductions in uncompensated care costs are passed onto insured populations, these estimates may be an overestimate.

estimated that 90,000 children would gain coverage. Given the differing scopes of these two interim final regulations, it is likely that more uninsured will be helped by PCIP than the patient protections policies and interim final regulations. Moreover, savings per person will likely be higher for the PCIP population compared to children with pre-existing conditions. This is because most enrollees in PCIP are likely to be adults, whose average cost of health care is higher than that of children.

In addition, we believe that PCIP will help local and State governments. Since much of the uncompensated health care is provided through State and locally funded public health facilities, by enabling a portion of those who would seek care at a public facility to enroll in the high risk pool, the program could help reduce the drain on scarce State and local resources. We welcome public comment on this analysis.

d. Costs and Transfers

Under section 1101 of the Affordable Care Act, HHS is authorized to disperse \$5 billion for the purpose of funding the PCIP program, including administrative costs and contracts with States and non-profit third party administrators. This Federal funding is used to offset the cost of providing health care to enrollees that exceeds the premium revenue. According to independent studies, the Federal share of total costs could be roughly 35 to 40 percent of total spending.³⁰

There will also be administrative costs associated with the PCIP program. This takes the form of the cost to contractors to apply, the time cost for individuals to apply, and the contractors' costs of complying with program rules (for example, conducting appeals, preventing fraud). The Department estimates that the annual administrative cost would be \$1.9 million. Note that any State administrative costs incurred that are allowable under this program may be paid for by Federal and premium funds.

e. Conclusion

Under section 1101 of the Affordable Care Act, the Department is authorized to spend \$5 billion via States and third party administrators for the purpose of funding the PCIP program. The transfer of this amount of funds will have a significant, positive financial impact on individuals who enroll in the program,

³⁰ Mark Merlis, "Health Coverage for the High-Risk Uninsured: Policy Options for Design of the Temporary High-Risk Pool," *National Institute for Health Care Reform, Center for Studying Health System Change* (2010).

States, and health care providers. We anticipate that individuals who are currently uninsured will benefit from having lower out-of-pocket costs for health care, less financial strain, and improved access to health services. We also anticipate that insured individuals will benefit indirectly through paying lower premiums because of a reduced burden on the plans to subsidize uncompensated care. In addition, we believe that establishing the PCIP program will reduce the burden on local and State governments to pay health care providers for uncompensated care.

The direct costs of this regulation is a transfer of \$5 billion from the Federal government to the PCIPs that will be established in each State.

Administrative costs are expected to be \$1.9 million per year. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

VII. Other Sections

Regulatory Alternatives

Under the Executive Order, we must consider alternatives to issuing regulations and alternative regulatory approaches. Section 1101 establishes broad requirements regarding contracting, eligibility, benefits, payments, insurer dumping, and the control of fraud, waste, and abuse.

We considered implementing the PCIP through some form of guidance to States and other interested parties. However, we believe that it is in the best interest of States, contractors, enrollees, and other interested parties to establish this program through the rulemaking process. As discussed in detail above, there are several areas where the statute clearly anticipates that the Secretary will exercise discretion in implementing the program, most notably the definition of a pre-existing condition for purpose of establishing eligibility. We also need to issue regulations to establish the legal framework for the contracting mechanism that sets the specific terms for the State-administered pools and for the organizations that will operate the pools in the States that do not contract with HHS. Establishing these rules through rulemaking ensures that the public has ample opportunity to understand and comment on these rules and establishes clear authority to enforce them.

The Department considered regulatory alternatives for program design, and often referred to the design features in existing State high risk pool and the Children's Health Insurance Program (CHIP) given their similarities to the PCIP goals and features. We

explored setting uniform rules for eligibility for all PCIPs but rejected this approach since it did not take into account the existing markets and programs in each State.

Given the fixed Federal funding for the PCIP program, these regulatory alternatives will not affect Federal outlays. They are also unlikely to have measurable national health spending implications since the Federal funding constraint is accompanied by a fixed standard for private premiums—100 percent of a standard rate for benefits that cover at least 65 percent of the cost of coverage.

Regulatory Flexibility Act

The RFA requires agencies that issue a regulation to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The Act 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.” These regulations apply to the States, both those that contract with HHS to establish PCIPs and those States in which HHS contracts with another entity to establish the program, no small entities will be affected. Therefore, the Secretary certifies that the regulations will not have significant impact on a substantial number of small entities.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates would require spending in any one year \$100 million in 1995 dollars, updated annually for inflation. In 2010, that threshold is approximately \$135 million.

UMRA does not address the total cost of a 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.

Under the Affordable Care Act, States may choose to participate in the PCIPs and receive Federal funding for administering and paying benefits. If they do not choose to participate, the Federal government will establish a

PCIPs in the State. Thus, the law and these regulations do not impose an unfunded mandate on States.

Individuals will have to pay a premium and incur out-of-pocket expenses to join the PCIPs that either a State or the Federal government establishes. However, individuals are free to join based on their evaluation of the costs and benefits of belonging to the program. There is no automatic enrollment and no requirement to join a PCIP. Thus, the law, and these regulations do not impose an unfunded mandate on the private sector.

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.

This rule does not impose any direct costs on State or local governments. Consistent with section 1101(g)(5) of the Act, § 152.40 of this interim final rule specifies that State standards that might otherwise apply to the coverage offered under a PCIP are preempted, with the exception of laws relating to licensing or solvency. This language tracks similar language that applies to State regulation of health plans offering Medicare Advantage plans under Medicare Part C or drug coverage under Medicare Part D under title XVIII of the Social Security Act, and we would expect to interpret the language for purposes of the high risk pool program in a manner similar to the way HHS has applied it under those programs. We do not anticipate that this regulation will have significant implications, particularly since only individuals who are not now insured, and thus not directly subject to existing State insurance laws, may enroll in the program.

List of Subjects in 45 CFR Part 152

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

■ For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR subtitle A, subchapter B, by adding a new part 152 to read as follows:

PART 152—PRE-EXISTING CONDITION INSURANCE PLAN PROGRAM

Subpart A—General Provisions

Sec.

- 152.1 Statutory basis.
- 152.2 Definitions.

Subpart B—PCIP Program Administration

- 152.6 Program administration.
- 152.7 PCIP proposal process.

Subpart C—Eligibility and Enrollment

- 152.14 Eligibility.
- 152.15 Enrollment and disenrollment process.

Subpart D—Benefits

- 152.19 Covered benefits.
- 152.20 Prohibitions on pre-existing condition exclusions and waiting periods.
- 152.21 Premiums and cost-sharing.
- 152.22 Access to services.

Subpart E—Oversight

- 152.26 Appeals procedures.
- 152.27 Fraud, waste, and abuse.
- 152.28 Preventing insurer dumping.

Subpart F—Funding

- 152.32 Use of funds.
- 152.33 Initial allocation of funds.
- 152.34 Reallocation of funds.
- 152.35 Insufficient funds.

Subpart G—Relationship to Existing Laws and Programs

- 152.39 Maintenance of effort.
- 152.40 Relation to State laws.

Subpart H—Transition to Exchanges

- 152.44 End of PCIP program coverage.
- 152.45 Transition to the exchanges.

Authority: Sec. 1101 of the Patient Protection and Affordable Care Act (Pub. L. 111–148).

Subpart A—General Provisions

§ 152.1 Statutory basis.

(a) *Basis.* This part establishes provisions needed to implement section 1101 of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), which requires the Secretary of the Department of Health and Human Services to establish a temporary high risk health insurance pool program to provide health insurance coverage for individuals described in § 152.14 of this part.

(b) *Scope.* This part establishes standards and sets forth the requirements, limitations, and procedures for the temporary high risk health insurance pool program, hereafter referred to as the “Pre-Existing Condition Insurance Plan” (PCIP) program.

§ 152.2 Definitions.

For purposes of this part the following definitions apply:

Creditable coverage means coverage of an individual as defined in section 2701(c)(1) of the Public Health Service Act as of March 23, 2010 and 45 CFR 146.113(a)(1).

Enrollee means an individual receiving coverage from a PCIP established under this section.

Lawfully present means

(1) A qualified alien as defined in section 431 of the Personal Responsibility and Work Opportunity Act (PRWORA) (8 U.S.C. 1641);

(2) An alien in nonimmigrant status who has not violated the terms of the status under which he or she was admitted or to which he or she has changed after admission;

(3) An alien who has been paroled into the United States pursuant to section 212(d)(5) of the Immigration and Nationality Act (INA) (8 U.S.C. 1182(d)(5)) for less than 1 year, except for an alien paroled for prosecution, for deferred inspection or pending removal proceedings;

(4) An alien who belongs to one of the following classes:

(i) Aliens currently in temporary resident status pursuant to section 210 or 245A of the INA (8 U.S.C. 1160 or 1255a, respectively);

(ii) Aliens currently under Temporary Protected Status (TPS) pursuant to section 244 of the INA (8 U.S.C. 1254a), and pending applicants for TPS who have been granted employment authorization;

(iii) Aliens who have been granted employment authorization under 8 CFR 274a.12(c)(9), (10), (16), (18), (20), (22), or (24);

(iv) Family Unity beneficiaries pursuant to section 301 of Public Law 101-649 as amended;

(v) Aliens currently under Deferred Enforced Departure (DED) pursuant to a decision made by the President;

(vi) Aliens currently in deferred action status;

(vii) Aliens whose visa petitions have been approved and who have a pending application for adjustment of status;

(5) A pending applicant for asylum under section 208(a) of the INA (8 U.S.C. 1158) or for withholding of removal under section 241(b)(3) of the INA (8 U.S.C. 1231) or under the Convention Against Torture who has been granted employment authorization, and such an applicant under the age of 14 who has had an application pending for at least 180 days;

(6) An alien who has been granted withholding of removal under the Convention Against Torture; or

(7) A child who has a pending application for Special Immigrant Juvenile status as described in section 101(a)(27)(J) of the INA (8 U.S.C. 1101(a)(27)(J)).

Out-of-pocket costs means the sum of the annual deductible and the other annual out-of-pocket expenses, other

than for premiums, required to be paid under the program.

Pre-Existing condition exclusion has the meaning given such term in 45 CFR 144.103.

Pre-Existing Condition Insurance Plan (PCIP) means the temporary high risk health insurance pool plan (sometimes referred to as a "qualified high risk pool") that provides coverage in a State, or combination of States, in accordance with the requirements of section 1101 of the Affordable Care Act and this part. The term "PCIP program" is generally used to describe the national program the Secretary is charged with carrying out, under which States or non-profit entities operate individual PCIPs.

Resident means an individual who has been legally domiciled in a State.

Service Area refers to the geographic area encompassing an entire State or States in which PCIP furnishes benefits.

State refers each of the 50 States and the District of Columbia.

Subpart B—PCIP Program Administration

§ 152.6 Program administration.

(a) *General rule.* Section 1101(b)(1) of the Affordable Care Act requires that HHS carry out the Pre-Existing Condition Insurance Plan program directly or through contracts with eligible entities, which are States or nonprofit private entities.

(b) *Administration by State.* A State (or its designated non-profit private entity) may submit a proposal to enter into a contract with HHS to establish and administer a PCIP in accordance with section 1101 of the Affordable Care Act and this part.

(1) At the Secretary's discretion, a State may designate a nonprofit entity or entities to contract with HHS to administer a PCIP.

(2) As part of its administrative approach, a State or designated entity may subcontract with either a for-profit or nonprofit entity.

(c) *Administration by HHS.* If a State or its designated entity notifies HHS that it will not establish or continue to administer a PCIP, or does not submit an acceptable or timely proposal to do so, HHS will contract with a nonprofit private entity or entities to administer a PCIP in that State.

(d) *Transition in administration.* The Secretary may consider a request from a State to transition from administration by HHS to administration by a State or from administration by a State to administration by HHS. Such transitions shall be approved only if the Secretary determines that the transition is in the best interests of the PCIP enrollees and

potential PCIP enrollees in that state, consistent with § 152.7(b) of this part.

§ 152.7 PCIP proposal process.

(a) *General.* A proposal from a State or nonprofit private entity to contract with HHS shall demonstrate that the eligible entity has the capacity and technical capability to perform all functions necessary for the design and operation of a PCIP, and that its proposed PCIP is in full compliance with all of the requirements of this part.

(b) *Special rules for transitions in administration.* (1) Transitions from HHS administration of a PCIP to State administration must take effect on January 1 of a given year.

(2) A State's proposal to administer a PCIP must meet all the requirements of this section.

(3) Transitions from State administration to HHS administration must comply with the termination procedures of the PCIP contract in effect with the State or its designated entity.

(4) The Secretary may establish other requirements needed to ensure a seamless transition of coverage for all existing enrollees.

Subpart C—Eligibility and Enrollment

§ 152.14 Eligibility.

(a) *General rule.* An individual is eligible to enroll in a PCIP if he or she:

(1) Is a citizen or national of the United States or lawfully present in the United States;

(2) Subject to paragraph (b) of this section, has not been covered under creditable coverage for a continuous 6-month period of time prior to the date on which such individual is applying for PCIP;

(3) Has a pre-existing condition as established under paragraph (c) of this section; and

(4) Is a resident of one of the 50 States or the District of Columbia which constitutes or is within the service area of the PCIP. A PCIP may not establish any standards with regard to the duration of residency in the PCIP service area.

(b) *Satisfaction of 6-month creditable coverage requirement when an enrollee leaves the PCIP service area.* An individual who becomes ineligible for a PCIP on the basis of no longer residing in the PCIP's service area as described in paragraph (a)(4) of this section is deemed to have satisfied the requirement in paragraph (a)(2) of this section for purposes of applying to enroll in a PCIP in the new service area.

(c) *Pre-existing condition requirement.* For purposes of establishing a process for determining eligibility, and subject

to HHS approval, a PCIP may elect to apply any one or more of the following criteria in determining whether an individual has a pre-existing condition for purposes of this section:

(1) *Refusal of coverage.* Documented evidence that an insurer has refused, or a clear indication that the insurer would refuse, to issue coverage to an individual on grounds related to the individual's health.

(2) *Exclusion of coverage.* Documented evidence that such individual has been offered coverage but only with a rider that excludes coverage of benefits associated with an individual's identified pre-existing condition.

(3) *Medical or health condition.* Documented evidence of the existence or history of certain medical or health condition, as approved or specified by the Secretary.

(4) *Other.* Other criteria, as defined by a PCIP and approved by HHS.

§ 152.15 Enrollment and disenrollment process.

(a) *Enrollment process.* (1) A PCIP must establish a process for verifying eligibility and enrolling an individual that is approved by HHS.

(2) A PCIP must allow an individual to remain enrolled in the PCIP unless:

- (i) The individual is disenrolled under paragraph (b) of this section;
- (ii) The individual obtains other creditable coverage;
- (iii) The PCIP program terminates, or is terminated; or
- (iv) As specified by the PCIP program and approved by HHS.

(3) A PCIP must verify that an individual is a United States citizen or national or lawfully present in the United States by:

- (i) Verifying the individual's citizenship, nationality, or lawful presence with the Commissioner of Security or Secretary of Homeland Security as applicable; or
- (ii) By requiring the individual to provide documentation which establishes the individual's citizenship, nationality, or lawful presence.

(iii) The PCIP must provide an individual who is applying to enroll in the PCIP with a disclosure specifying if the information will be shared with the Department of Health and Human Services, Social Security Administration, and if necessary, Department of Homeland Security for purposes of establishing eligibility.

(b) *Disenrollment process.* (1) A PCIP must establish a disenrollment process that is approved by HHS.

(2) A PCIP may disenroll an individual if the monthly premium is

not paid on a timely basis, following notice and a reasonable grace period, not to exceed 61 days from when payment is due, as defined by the PCIP and approved by HHS.

(3) A PCIP must disenroll an individual in any of the following circumstances:

- (i) The individual no longer resides in the PCIP service area.
- (ii) The individual obtains other creditable coverage.
- (iii) Death of the individual.
- (iv) Other exceptional circumstances established by HHS.

(c) *Effective dates.* A PCIP must establish rules governing the effective date of enrollment and disenrollment that are approved by HHS. A complete enrollment request submitted by an eligible individual by the 15th day of a month, where the individual is determined to be eligible for enrollment, must take effect by the 1st day of the following month, except in exceptional circumstances that are subject to HHS approval.

(d) *Funding limitation.* A PCIP may stop taking applications for enrollment to comply with funding limitations established by the HHS under section 1101(g) of Public Law 111-148 and § 152.35 of this part. Accordingly, a PCIP may employ strategies to manage enrollment over the course of the program that may include enrollment capacity limits, phased-in (delayed) enrollment, and other measures, as defined by the PCIP and approved by HHS, including measures specified under § 152.35(b).

Subpart D—Benefits

§ 152.19 Covered benefits.

(a) *Required benefits.* Each benefit plan offered by a PCIP shall cover at least the following categories and the items and services:

- (1) Hospital inpatient services
- (2) Hospital outpatient services
- (3) Mental health and substance abuse services
- (4) Professional services for the diagnosis or treatment of injury, illness, or condition
- (5) Non-custodial skilled nursing services
- (6) Home health services
- (7) Durable medical equipment and supplies
- (8) Diagnostic x-rays and laboratory tests
- (9) Physical therapy services (occupational therapy, physical therapy, speech therapy)
- (10) Hospice
- (11) Emergency services, consistent with § 152.22(b), and ambulance services

(12) Prescription drugs

(13) Preventive care

(14) Maternity care

(b) *Excluded services.* Benefit plans offered by a PCIP shall not cover the following services:

(1) Cosmetic surgery or other treatment for cosmetic purposes except to restore bodily function or correct deformity resulting from disease.

(2) Custodial care except for hospice care associated with the palliation of terminal illness.

(3) In vitro fertilization, artificial insemination or any other artificial means used to cause pregnancy.

(4) Abortion services except when the life of the woman would be endangered or when the pregnancy is the result of an act of rape or incest.

(5) Experimental care except as part of an FDA-approved clinical trial.

§ 152.20 Prohibitions on pre-existing condition exclusions and waiting periods.

(a) *Pre-existing condition exclusions.* A PCIP must provide all enrollees with health coverage that does not impose any pre-existing condition exclusions (as defined in § 152.2) with respect to such coverage.

(b) *Waiting periods.* A PCIP may not impose a waiting period with respect to the coverage of services after the effective date of enrollment.

§ 152.21 Premiums and cost-sharing.

(a) *Limitation on enrollee premiums.*

(1) The premiums charged under the PCIP may not exceed 100 percent of the premium for the applicable standard risk rate that would apply to the coverage offered in the State or States. The PCIP shall determine a standard risk rate by considering the premium rates charged for similar benefits and cost-sharing by other insurers offering health insurance coverage to individuals in the applicable State or States. The standard risk rate shall be established using reasonable actuarial techniques, that are approved by the Secretary, and that reflect anticipated experience and expenses. A PCIP may not use other methods of determining the standard rate, except with the approval of the Secretary.

(2) Premiums charged to enrollees in the PCIP may vary on the basis of age by a factor not greater than 4 to 1.

(b) *Limitation on enrollee costs.* (1) The PCIP's average share of the total allowed costs of the PCIP benefits must be at least 65 percent of such costs.

(2) The out-of-pocket limit of coverage for cost-sharing for covered services under the PCIP may not be greater than the applicable amount described in section 223(c)(2) of the Internal Revenue

code of 1986 for the year involved. If the plan uses a network of providers, this limit may be applied only for in-network providers, consistent with the terms of PCIP benefit package.

§ 152.22 Access to services.

(a) *General rule.* A PCIP may specify the networks of providers from whom enrollees may obtain plan services. The PCIP must demonstrate to HHS that it has a sufficient number and range of providers to ensure that all covered services are reasonably available and accessible to its enrollees.

(b) *Emergency services.* In the case of emergency services, such services must be covered out of network if:

(1) The enrollee had a reasonable concern that failure to obtain immediate treatment could present a serious risk to his or her life or health; and

(2) The services were required to assess whether a condition requiring immediate treatment exists, or to provide such immediate treatment where warranted.

Subpart E—Oversight

§ 152.26 Appeals procedures.

(a) *General.* A PCIP shall establish and maintain procedures for individuals to appeal eligibility and coverage determinations.

(b) *Minimum requirements.* The appeals procedure must, at a minimum, provide:

(1) A potential enrollee with the right to a timely redetermination by the PCIP or its designee of a determination regarding PCIP eligibility, including a determination of whether the individual is a citizen or national of the United States, or is lawfully present in the United States.

(2) An enrollee with the right to a timely redetermination by the PCIP or its designee of a determination regarding the coverage of a service or the amount paid by the PCIP for a service.

(3) An enrollee with the right to a timely reconsideration of a redetermination made under paragraph (b)(2) of this section by an entity independent of the PCIP.

§ 152.27 Fraud, waste, and abuse.

(a) *Procedures.* The PCIP shall develop, implement, and execute operating procedures to prevent, detect, recover (when applicable or allowable), and promptly report to HHS incidences of waste, fraud, and abuse, and to appropriate law enforcement authorities instances of fraud. Such procedures shall include identifying situations in which enrollees or potential enrollees

(or their family members) are employed, and may have, or have had, access to other coverage such as group health coverage, but were discouraged from enrolling.

(b) *Cooperation.* The PCIP shall cooperate with Federal law enforcement and oversight authorities in cases involving waste, fraud and abuse, and shall report to appropriate authorities situations in which enrollment in other coverage may have been discouraged.

§ 152.28 Preventing insurer dumping.

(a) *General rule.* If it is determined based on the procedures and criteria set forth in paragraph (b) of this section that a health insurance issuer or group health plan has discouraged an individual from remaining enrolled in coverage offered by such issuer or health plan based on the individual's health status, if the individual subsequently enrolls in a PCIP under this part, the issuer or health plan will be responsible for any medical expenses incurred by the PCIP with respect to the individual.

(b) *Procedures and criteria for a determination of dumping.* A PCIP shall establish procedures to identify and report to HHS instances in which health insurance issuers or employer-based group health plans are discouraging high-risk individuals from remaining enrolled in their current coverage in instances in which such individuals subsequently are eligible to enroll in the qualified high risk pool. Such procedures shall include methods to identify the following circumstances, either through the PCIP enrollment application form or other vehicles:

(1) Situations where an enrollee or potential enrollee had prior coverage obtained through a group health plan or issuer, and the individual was provided financial consideration or other rewards for disenrolling from their coverage, or disincentives for remaining enrolled.

(2) Situations where enrollees or potential enrollees had prior coverage obtained directly from an issuer or a group health plan and either of the following occurred:

(i) The premium for the prior coverage was increased to an amount that exceeded the premium required by the PCIP (adjusted based on the age factors applied to the prior coverage), and this increase was not otherwise explained;

(ii) The health plan, issuer or employer otherwise provided money or other financial consideration to disenroll from coverage, or disincentive to remain enrolled in such coverage. Such considerations include payment of the PCIP premium for an enrollee or potential enrollee.

(c) *Remedies.* If the Secretary determines, based on the criteria in paragraph (b) of this section, that the rule in paragraph (a) of this section applies, an issuer or a group health plan will be billed for the medical expenses incurred by the PCIP. The issuer or group health plan also will be referred to appropriate Federal and State authorities for other enforcement actions that may be warranted based on the behavior at issue.

(d) *Other.* Nothing in this section may be construed as constituting exclusive remedies for violations of this section or as preventing States from applying or enforcing this section or other provisions of law with respect to health insurance issuers.

Subpart F—Funding

§ 152.32 Use of funds.

(a) *Limitation on use of funding.* All funds awarded through the contracts established under this program must be used exclusively to pay allowable claims and administrative costs incurred in the development and operation of the PCIP that are in excess of the amounts of premiums collected from individuals enrolled in the program.

(b) *Limitation on administrative expenses.* No more than 10 percent of available funds shall be used for administrative expenses over the life of the contract with the PCIP, absent approval from HHS.

§ 152.33 Initial allocation of funds.

HHS will establish an initial ceiling for the amount of the \$5 billion in Federal funds allocated for PCIPs in each State using a methodology consistent with that used to establish allocations under the Children's Health Insurance Program, as set forth under 42 CFR Part 457, Subpart F, Payment to States.

§ 152.34 Reallocation of funds.

If HHS determines, based on actual and projected enrollment and claims experience, that the PCIP in a given State will not make use of the total estimated funding allocated to that State, HHS may reallocate unused funds to other States, as needed.

§ 152.35 Insufficient funds.

(a) *Adjustments by a PCIP to eliminate a deficit.* In the event that a PCIP determines, based on actual and projected enrollment and claims data, that its allocated funds are insufficient to cover projected PCIP expenses, the PCIP shall report such insufficiency to HHS, and identify and implement

necessary adjustments to eliminate such deficit, subject to HHS approval.

(b) *Adjustment by the Secretary.* If the Secretary estimates that aggregate amounts available for PCIP expenses will be less than the actual amount of expenses, HHS reserves the right to make such adjustments as are necessary to eliminate such deficit.

Subpart G—Relationship to Existing Laws and Programs

§ 152.39 Maintenance of effort.

(a) *General.* A State that enters into a contract with HHS under this part must demonstrate, subject to approval by HHS, that it will continue to provide funding of any existing high risk pool in the State at a level that is not reduced from the amount provided for in the year prior to the year in which the contract is entered.

(b) *Failure to maintain efforts.* In situations where a State enters into a contract with HHS under this part, HHS shall take appropriate action, such as terminating the PCIP contract, against any State that fails to maintain funding levels for existing State high risk pools as required, and approved by HHS, under paragraph (a) of this section.

§ 152.40 Relation to State laws.

The standards established under this section shall supersede any State law or regulation, other than State licensing laws or State laws relating to plan solvency, with respect to PCIPs which are established in accordance with this section.

Subpart H—Transition to Exchanges

§ 152.44 End of PCIP program coverage.

Effective January 1, 2014, coverage under the PCIP program (45 CFR part 152) will end.

§ 152.45 Transition to the exchanges.

Prior to termination of the PCIP program, HHS will develop procedures to transition PCIP enrollees to the Exchanges, established under sections 1311 or 1321 of the Affordable Care Act, to ensure that there are no lapses in health coverage for those individuals.

Dated: July 26, 2010.

Jay Angoff,

Director, Office of Consumer Information and Insurance Oversight.

Dated: July 26, 2010.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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