

Pre-Existing Condition Insurance Plan
Interim Final Rule with Comment
SUMMARY

August 3, 2010

On July 29, 2010, the Office of Consumer Information and Insurance Oversight (OCIIO) of the Department of Health and Human Services (HHS) released an Interim Final Rule with request for comment implementing the provisions of the Patient Protection and Affordable Care Act (P.L. 111-148) relating to creation of a temporary high-risk pool for uninsured individuals with pre-existing conditions. The rule is published in the *Federal Register* for July 30, 2010 (pp. 45014-45033) and is effective as of that date. **The 60-day comment period ends on September 28, 2010.** Written comments should be submitted to OCIIO.

I. BACKGROUND

Thirty-five state high risk pools currently provide coverage to approximately 200,000 individuals, or about one percent of the individual health insurance market nationwide. These pools vary in terms of the populations they cover and the benefits they provide (and a few are closed to enrollment). These state high-risk pools serve as an alternative source of coverage in the event that an insurer in the individual market denies them coverage or, in some states, only offer them coverage at a prohibitively high premium. States without risk pools may require insurers to accept all applicants (a requirement called guaranteed issue) or may provide for an “insurer of last resort,” often a non-profit Blue Cross Blue Shield plan which is exempt from state insurance taxes in return for insuring high risk individuals.

The Patient Protection and Affordable Care Act (ACA) applies a ban on pre-existing condition exclusions and “rate-ups” based on health status starting in 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 and for all individuals on or after January 1, 2014. Under section 1101 of the ACA, the Secretary of HHS is required to 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 preexisting conditions. This program will operate until January 1, 2014 when the health insurance exchanges, guarantee issue requirement and general prohibition on the use by issuers and health plans of preexisting condition exclusions take effect.

On April 2, 2010, HHS Secretary Kathleen Sebelius issued a letter to governors and state insurance commissioners asking each state to express its interest in participating in this program. To differentiate the new temporary program from the existing state high risk pool programs, HHS has designated it as the **Pre-Existing Condition Insurance Plan program**, or **PCIP**. Twenty-eight states requested that they run the program themselves; 18 states responded to request that the federal government run their PCIP. The plan

operated by HHS will be run in conjunction with the Office of Personnel Management and the Department of Agriculture's National Finance Center. The Government Employees Health Association (GEHA) is the contractor that has been engaged to administer the HHS PCIP. The Secretary's solicitation as well as the model contract between HHS and the states (or non-profit private entity) for operating the PCIP (High-Risk Pool Model Contract) is available at: www.hhs.gov/ociio/initiative/index.html

This interim final rule implements key aspects of the PCIP program such as program administration, eligibility and enrollment, benefits, premiums, funding, and appeals and oversight rules.

II. OVERVIEW OF THE REGULATIONS

Definition of a Pre-Existing Condition (§152.2)

The interim final rule defines a “pre-existing condition” as—

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.

In the case of determining eligibility for a PCIP, “pre-existing condition” is determined based on whether an individual has been refused for coverage or other criteria specified below (see “Eligibility Based on Having a Pre-Existing Condition.”)

The rule also defines other terms, including “lawfully present,” “pre-existing condition exclusion,” and other terms used below.

PCIP Program Administration and Proposal Process (§152.6; §152.7)

The interim final rule specifies general rules for administration of the PCIP program through either a state or by HHS through a non-profit private entity. It describes the proposal process and specifies that in order to contract with HHS, an 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 be in full compliance with all related requirements. Minimum requirements for PCIPs are also established in the rule. Additional requirements are detailed in solicitation documents (for example, the descriptions of the outreach plan and consumer information resources that each PCIP will establish) and also incorporated into the final contracts with HHS.

Also under the rule, the Secretary of HHS may consider a request from a state to transition from administration by HHS to administration by a state or vice versa but such transitions shall be approved only if the Secretary determines that the transition is in the

best interests of the PCIP enrollees and potential enrollees. Such transitions are to take effect on January 1 of a given year.

Subpart C—Eligibility and Enrollment

Eligibility (§152.14)

The ACA provides that an individual is eligible to enroll in a PCIP if he or she: (1) is a citizen or national of the U.S. or is lawfully present in the U.S. as determined in accordance with section 1411 of the ACA; (2) has not been covered under creditable coverage (defined below) 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. The rule further requires 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. As noted above, eligibility for the PCIP program is limited to U.S. citizens or nationals and individuals who are lawfully present in the country. The term “lawfully present” has the same meaning under the rule as under the State Children’s Health Insurance Program (CHIP), provided in the State Health Official letter issued by the Centers for Medicare and Medicaid Services (CMS) on July 1, 2010.

The ACA 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. The rule specifies the type of information that applicants must provide and verification procedures that the HHS Secretary, Commissioner of Social Security, and Secretary of the Department of Homeland Security (DHS) are required to follow to establish eligibility.

The ACA requires that the HHS Secretary conduct verifications and determinations “through the use of an online 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 rule, the *PCIP is required to verify that an individual is a U.S. citizen or national, or lawfully present.* This can be done through the Social Security Administration (SSA) or, if applicable, the DHS. States may automate verification of citizenship and immigration status by leveraging existing data exchanges currently in place for other programs, such as Medicaid and CHIP.¹ An automated verification process will be used in all states where HHS is administering the PCIP program.

¹ The DHS’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.

For states unable to have an automated on-line system or electronic process in place when they start accepting enrollments into their PCIPs, an alternative method may be used, as approved by the Secretary, whereby 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 SSA or the DHS, consistent with the Privacy Act, 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. The ACA limits eligibility for the PCIP program to individuals with no creditable coverage during the six-month period prior to when they apply for coverage through the PCIP. Under current law and regulation, creditable coverage is defined as coverage of an individual under a group health plan, health insurance coverage,² Medicare Part A or Part B, Medicaid, CHIP, the TRICARE program, a medical care program of the Indian Health Service or of a tribal organization, a state health benefits risk pool (i.e., existing state high risk pool), the Federal Employee Health Benefits program, a public health plan (e.g., coverage through the Veterans Administration), or a health benefit plan offered under section 5(e) of the Peace Corps Act. Such creditable coverage includes 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).

An individual who has already satisfied the requirement for a 6-month period without creditable coverage in connection with qualifying for a given PCIP will be considered to have satisfied this eligibility requirement for purposes of a PCIP in another state, should that person move and want to enroll in the other state's PCIP. HHS intends to issue guidance on how an infant who is less than six months old can satisfy the eligibility requirement. Factors to be considered include whether coverage in the hospital under the mother's plan at birth counts, current practices regarding insurers' coverage of newborns, and the ACA's anti-dumping rules for the PCIP program that direct the Secretary of HHS to prevent disenrollment of individuals from existing insurance due to their health status.

Eligibility Based on Having a Pre-Existing Condition. The ACA conditions eligibility for the PCIP program on individuals having a pre-existing condition, as "determined in a manner consistent with guidance issued by the Secretary." Under this interim final rule, a PCIP may determine that an individual has a preexisting condition, for purposes of eligibility, based on satisfying any one or more of the following criteria, subject to HHS approval:

²Health insurance coverage is defined in title XXVII of the PHS Act and 45 CFR 144.103 benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or HMO contract offered by a health insurance issuer.

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.

Because individuals with pre-existing conditions are sometimes unable to obtain outright written coverage denials, but instead are told that insurers will not accept their applications, HHS is permitting PCIPs to exercise flexibility in determining exactly what type of communication constitutes a refusal to issue coverage. In addition, states that require insurers to provide coverage on a guaranteed issue basis and to community rate their premiums may want to use the second criteria described above as an alternative to one requiring the individual to document a denial of coverage.

HHS anticipates 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 operated by HHS, 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 live in the PCIP's service area. A service area is defined by the rule as one of the 50 states or the District of Columbia. The ACA does not provide for the operation of a PCIP in Territories.

Enrollment and Disenrollment Process (§152.15)

Enrollment Process. PCIPs are required to establish a process for enrolling and disenrolling individuals that is approved by HHS. The Department intends 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 ACA. A PCIP must allow an individual to remain enrolled unless the individual is disenrolled under specified circumstances (e.g., moving out of the service area or obtaining other creditable coverage) or the PCIP program is terminated.

Disenrollment Process. In the event that an enrollee fails to pay their PCIP premium, HHS is requiring that the enrollee receive sufficient notice and reasonable grace period for payment prior to any disenrollment taking effect (not to exceed 61 days, which is the longest period currently provided for by states). Other circumstances where involuntary disenrollment is appropriate are also described (death, becoming covered under creditable

coverage, fraud or intentional misrepresentation of material fact). HHS intends to work with PCIPs to develop policies in these areas via sub-regulatory guidance.

Effective Dates of Enrollment. In general, the rule provides that an individual who submits a complete enrollment request to a PCIP by the 15th day of a month be able to access coverage by the first day of the following month. Exceptions to this policy are subject to approval by HHS.

Funding Limitation. Finally, given the capped appropriation for this program (see “Funding” below), the rule permits a PCIP program to employ strategies to manage enrollment that may include enrollment capacity limits, phased-in (delayed) enrollment and other measures (such as premium and benefit adjustments that indirectly affect enrollment), as defined by the PCIP and approved by HHS.

Subpart D—Benefits

Covered Benefits (§152.19)

Required Benefits. The required benefits for the PCIP build off of the *essential health benefits* which are established under the ACA. Guidance has not been issued specifying the essential health benefits package. HHS observes, however, that the statutory list of essential health benefits is consistent with the most commonly covered services offered in existing state high risk pools and are also parallel to the benefits offered by the Federal Employees Health Benefits Plan (FEHBP). The rule lists the essential benefits.

Excluded Services. Excluded services are as follows:

- Cosmetic surgery (except to restore bodily function or correct deformity resulting from disease);
- Custodial care except for hospice care associated with the palliation of terminal illness;
- In vitro fertilization, artificial insemination or any other artificial mean used to cause pregnancy;
- 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; and
- Experimental care except as part of an FDA-approved clinical trial.

HHS discusses in the rule’s preamble the exclusion of elective abortions, a policy that is consistent with the exclusion of federally funded elective abortions under other parts of the ACA.

Pre-Existing Conditions Exclusions (§152.20)

The ACA and the interim final rule prohibit a PCIP from imposing any pre-existing condition exclusions with respect to covered services. The rule also prohibits PCIPs from imposing any type of coverage waiting period upon eligible individuals. 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, full coverage must be provided to the individual starting with the effective date of enrollment.

Premiums and Cost-Sharing (§152.21)

The ACA requires that premium rates charged for coverage under the high risk pool program be established at “a standard rate for a standard population”. In keeping with the methodology suggested by the NAIC Model Health Plan for Uninsurable Individuals and the existing Federal grant program for state high-risk pools (first established under the Trade Act of 2002), the interim final rule interprets the phrase “standard rate for a standard population” to refer to the premium rates offered in the individual market in a given state. A PCIP may calculate the standard rate using reasonable actuarial techniques, approved by the Secretary, that reflect anticipated experience and expenses.

HHS explains in the rule’s preamble that while existing state high risk pools’ premiums vary between 105–250% of the standard rate of the individual market, the ACA “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.” However, because individual market rates in each state can vary as a consequence of individual state insurance laws (e.g., some states require guaranteed issue or community rating), the rule provides that a PCIP may use other methods of determining the standard rate with the approval of HHS. The exact methodology must be submitted and approved to HHS as part of the PCIP’s proposal

Premium Variation. The ACA and the interim final rule permit PCIP premium rates to vary on the basis of age by a factor not greater than 4 to 1 but also require HHS to define permissible age bands for rating purposes in the individual and group markets effective January 1, 2104. The rule does not establish standard age bands for the PCIP program, however. HHS explains in the preamble that specific age band rating will be established through the PCIP contracting process. Also, HHS clarifies that a PCIP may use other rating factors as permitted under section 2701 of the Act. (This limits variation to age, as noted, as well as geography, individual or family coverage, and tobacco use within specified limits.) Accordingly, gender rating, for example, is prohibited in the PCIP program.

Limits on Enrollee Costs. Under the ACA, the issuer’s share of the total allowed costs of benefits provided under PCIP coverage cannot be less than 65% of such costs, subject to actuarial review and approval by the Secretary. Consistent with the Act, the interim final rule provides that coverage under a plan offered by a PCIP must at a minimum meet this 65% threshold. In addition, the statute and the rule require that coverage provided by PCIPs not have an out-of-pocket limit greater than the out-of-pocket limit for high deductible health plans associated with tax favored health savings accounts (HSAs). (This amount is \$5,950 for 2010.) Out-of-pocket costs are defined in the rule (§152.2) 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. As is true for the Internal Revenue Service rules for HSA-qualified high deductible plans, the out-of-pocket limit may be applied only for in-network providers, consistent with the terms of the PCIP plan benefit package.

Access to Services (§152.22)

Under the interim final rule, a 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. Emergency room 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.

Subpart E—Oversight

Appeals Procedures (§152.26)

The ACA requires the establishment of an appeals process to enable individuals to appeal determinations under the PCIP program. HHS is interpreting the statutory requirement to apply both to determinations with respect to benefit coverage determinations and with respect to an individual's eligibility for the program. Given the temporary nature of the program and the required timeframe for its implementation, HHS intends the specific requirements to permit states to use existing appeals or review mechanisms provided 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. Specifically, a PCIP must at a minimum:

- 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);
- Provide an enrollee with the right to a timely second-level appeal, or "reconsideration," by an independent entity. As explained by the rule's preamble, this 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.

Fraud, Waste, and Abuse (§152.27)

The ACA requires the Secretary to establish procedures to protect against fraud, waste, and abuse. Under the interim final rule, a PCIP is required 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. PCIPs should include procedures designed to identify 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. HHS notes that noncompliance will lead it to take appropriate action within the terms of the contract, or as otherwise provided by law. Also under the rule, a PCIP must cooperate with federal law enforcement and oversight authorities in cases involving waste, fraud and abuse, and must report cases in which an individual may have been discouraged from enrolling in other coverage to appropriate authorities.

Preventing Insurer Dumping (§152.28)

The ACA requires the Secretary of HHS 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 their health status and specifies certain criteria that the Secretary must include in the criteria. Implementing this requirement, the interim final rule 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. Dumping situations are described in the rule (e.g., where the premium for the prior coverage was increased to an amount that exceeded the PCIP premium and the increase was not otherwise explained.) If the Secretary determines that a “dumping” has occurred, the issuer or group health plan will be responsible 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.

The rule also notes that it is not meant to provide for exclusive remedies for violations of the section or preventing states from applying or enforcing the section or other provisions of law with respect to health insurance issuers. HHS advises that additional guidance will be issued to prevent “dumping” from public programs like Medicaid and CHIP.

Subpart F—Funding

Use of Funds (§152.32)

The ACA appropriates \$5 billion to pay the claims and administrative costs of the PCIP program that are in excess of the amount of premiums collected from enrollees. The rule provides that all funds awarded under this program must be used exclusively to pay the allowable claims and administrative costs of a PCIP. In the rule’s preamble, HHS notes that 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 ACA does not specify the amount that a PCIP can spend on administrative expenses, the rule provides that PCIPs spend no more than 10% of its total allotted funds towards administrative expenses. Examples of administrative costs provided by the preamble 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. Under the rule, the 10% 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)

The ACA does not specify how the appropriated funds are to be allocated. The rule provides that the Secretary establish initial allotment ceilings for PCIPs in each state using a methodology consistent with the funding allocation methodology used in CHIP.

HHS explains in the preamble that subject to the allocation ceilings, 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.

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. The rule's preamble details the methodology and data use to do allocate the funding.

Reallocation of Funds (§152.34)

Because a need may arise to reallocate funds if actual experience indicates that, in a given state, not all of the funds available under the allocation formula will be used, the rule authorizes HHS to reallocate funds among states.

Insufficient Funds (§152.35)

Under the ACA, if HHS estimates for any fiscal year that the aggregate amounts available for the payment of the expenses of the temporary high risk pool program will be less than the actual amount of such expenses, it shall make adjustments to eliminate this deficit. The statute also authorizes HHS to stop taking applications for participation in the program to comply with the funding limitations. The implementing rule permits the PCIP to adjust premiums, alter required benefits, limit PCIP applications or take other measures to eliminate a projected deficit, as approved by HHS. HHS intends to closely

monitor PCIP enrollment and claims experience to assess the use of program funding and to that end, the PCIP contracts include detailed reporting responsibilities with respect to PCIP enrollment and spending. The contracts also specify PCIP responsibilities for the development of mitigation strategies and recommended adjustments in the event that the amounts available under a contract are less than the projected expenses. The rule also states that HHS reserves the right to make such adjustments as are necessary to eliminate a deficit, consistent with the terms of the PCIP contract.

Subpart G—Relationship to Existing Laws and Programs

The rule’s preamble explains that the insurance reform provisions elsewhere in the ACA do not apply to the PCIP since the high risk insurance pool does not meet the definition of a group health plan or a health insurance issuer.

Maintenance of Effort (§152.39)

The ACA requires that in order for a state to enter into a contract to administer a PCIP, the state must agree not to reduce the annual amount it expended on the operation of its high risk pool in the year preceding the year in which a PCIP contract begins. In the view of HHS, “the clear intent of this provision is to prohibit the shifting of costs of existing state high risk pools to the Federal government.” In implementing this provision, however, HHS recognizes that states use different sources of funds to support the operation of existing high risk pools (e.g., assessments on insurers or providers). “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, the rule provides that in order for a state to enter into a contract with the Secretary, it must comply with the maintenance of effort requirement set in a manner approved by the Secretary. The rule’s preamble notes that permissible methods of meeting this requirement are likely to include, but not be 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 pool. Again, all such approaches are subject to the approval of the Secretary.

In situations where a state enters into a contract with HHS to provide a PCIP, 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 (§152.39)

As provided under the ACA, the rule specifies that 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. HHS observes in the preamble that it expects to interpret the federal preemption in a manner similar to the way it has applied it with respect to Medicare Advantage and Medicare Part D.

Subpart H-Transition to Exchanges

The ACA calls for termination of the temporary high risk pool program as of January 1, 2014, when coverage will be available under the Exchanges and insurance plans will no longer be permitted to exclude coverage for preexisting conditions. The preamble notes 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. Since the Exchanges are still in the developmental stages, HHS says that it would be premature to specify transition procedures in this interim final rule. Such rules will be developed in the future. **HHS seeks comments on the best ways to carry out the transition.**

III. RESPONSE TO COMMENTS

HHS will consider all comments received by the September 28, 2010 deadline and will respond to comments in the preamble when it proceeds with a subsequent document.

IV. WAIVER OF PROPOSED RULEMAKING

HHS found good cause that using a notice-and-comment procedure before implementing a final rule is impracticable and contrary to the public interest in this case because of the short time provided under the ACA to put a high risk pool program in place (no later than 90 days after enactment). Therefore, this final rule was issued on an interim basis with a 60-day public comment period provided.

V. COLLECTION OF INFORMATION REQUIREMENTS (PAPERWORK REDUCTION ACT)

Under the Paperwork Reduction Act provisions for notice and comment on information collection requirements, HHS must solicit public comment with respect to certain information collection requirements which are listed below. In each case comments are sought on: 1) the need for the information collection, 2) the accuracy of their estimates of the information collection burden, 3) the quality, utility and clarity of the information to be collected, and 4) recommendations for minimizing the collection burden, including automated collection techniques.

The specific information collection requirements involve the process for states (or nonprofit entities in the absence of a state proposal) to propose operation of a PCIP, a one-time collection burden. HHS estimates that 684 hours are required to comply with this requirement, which includes the time and effort needed to establish enrollment and disenrollment procedures, demonstrate an adequate number and range of providers, develop and maintain appeals procedures, and demonstrate maintenance of effort with respect to existing state high risk pools. The Department expects that while uncommon,

states or contractors may wish to amend their approved PCIP contract, and submitting a revised proposal and implementing any approved amendments would require an estimated 24 hours per contractor (state or nonprofit entity). Meeting requirements that PCIPs report instances of waste, fraud and abuse is estimated to require 4 hours a month while 8 hours a month is the estimated requirement for reporting to HHS regarding any health insurer or group plan identifies as having discouraged an individual from remaining enrolled based on health status (§152.28). The time estimated for states to collect allowable cost information and review and submit it to HHS for payment is 16 hours a month. Additionally, HHS estimates that it will take about 30 minutes for individual PCIP applicants to obtain review and submit proof of eligibility. Table 1 of the interim final rule (75 FR 45024) provides a summary of these estimates

Comments will be accepted through September 28, 2010, after which an additional 30-day comment period will commence with the publication by HHS of a notice announcing the submission of the information collection request for approval by the Office of Management and Budget (OMB). (Comments on the information collection requirements may be submitted to the OMB Office of Regulatory Affairs at OIRA_submission@omb.eop.gov as an alternative to submission to the ADDRESS ABOVE.)

VI. REGULATORY IMPACT ANALYSIS

In summary, HHS states the PCIP program will have a significant, positive financial impact on individuals who enroll, and on states and health care providers. Individuals who are currently uninsured will benefit from lower out of pocket expenditures for health care, less financial strain, and improved access to services. Insured individuals will benefit indirectly from reduced cost-shifting to cover uncompensated care. HHS believes that PCIP will reduce the burden on state and local governments to pay health care providers for uncompensated care.

OMB has determined that the regulation is economically significant, meaning that it is likely that it will have an annual effect on the economy of \$100 million in any one year. The interim final rule provides a summary of the benefits, costs and transfers associated with the regulations.

Estimated Number of Affected Entities

With respect to potential enrollment, HHS refers to analyses by the Center for Studying Health Systems Change, the CMS Office of the Actuary, and the Congressional Budget Office in estimating that between 200,000 and 400,000 individuals are likely to enroll in the PCIP program. (No new analysis was produced for the purpose of this rule.) HHS points out that even the lower estimate would double the number of Americans with pre-existing conditions insured through high risk pool programs. The Department expects that the \$5 billion in funding provided through the ACA will be sufficient to meet program demand, and 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...”

In discussing this estimate, HHS notes that there are 35 state-based high risk pool programs in existence today, but that it is difficult to extrapolate from the experience of these programs to the new federal program established under the ACA because of differences between them. These include the federal program’s limit on eligibility to those who have gone without insurance for at least 6 months; its immediate coverage of pre-existing conditions without use of carve-outs and waiting periods like most state programs, lower premiums in the federal program, and high variation in participation rates among the state programs.

Benefits

HHS states that the interim final regulation could generate significant benefits to consumers, and **welcomes public comment on its analysis**. Benefits specifically identified are reductions in mortality and morbidity, reductions in financial burden faced by the uninsured, increases in worker productivity, and decreases in cost shifting of uncompensated care to the privately insured. In discussing these benefits, literature is cited describing to the impact of expanding health insurance coverage on health improvements, the financial burdens faced by the uninsured, the positive effects of insurance coverage on the labor market, and estimates of reduced cost-shifting associated with uncompensated care. In the latter case, HHS cites in particular the analysis offered by the Departments of Labor, Treasury and HHS in the interim final regulations implementing patient protections.

Costs and Transfers

In addition to the \$5 billion directly appropriated under the ACA, HHS estimates that the administrative costs associated with the PCIP program will total \$1.9 million annually. This includes the cost of contractors (states or nonprofits) and individuals to apply, and the contractors’ costs of complying with program rules. Allowable state administrative costs may be financed by federal and premium funds.

VII. OTHER SECTIONS

Regulatory Alternatives

HHS reports that it considered implementing PCIP through guidance to states, rather than the rulemaking process but concluded that rulemaking with notice and comment is preferred because of the discretion provided the Secretary, particularly in defining pre-existing condition for the purposes of eligibility. In addition, HHS states regulations are required to establish the legal contracting mechanism for operating the pools. With respect to program design, the alternative of uniform rules for all PCIPs was rejected because it would not take into account variations in existing state programs and insurance markets.

Regulatory Flexibility Act

Because the regulations apply to state governments, HHS asserts they will not have a significant impact on a substantial number of small entities as defined under the Regulatory Flexibility Act.

Unfunded Mandates Reform Act

HHS states that the regulations do not impose an unfunded mandate on states, which may choose to participate in PCIPs and receive federal funding to do so. Additionally, HHS states no unfunded mandate is imposed on the private sector because there is no automatic enrollment of individuals or requirement to join a PCIP.

Federalism Statement

HHS states that the rule does not impose any direct costs on state or local governments, and HHS does not believe the regulation will have significant federal implications with respect to state insurance laws. State standards that might otherwise apply to coverage offered under a PCIP are pre-empted (except with respect to licensing or solvency), using language that applies to state regulation of Medicare Advantage plans and Medicare Part D prescription drug plans. Because only individuals who are uninsured and not subject to state insurance laws will be eligible to enroll in the program, HHS does not anticipate significant implications.