

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 152

[CMS-9995-IFC3]

RIN 0938-AQ70

Pre-Existing Condition Insurance Plan Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period sets the payment rates for covered services furnished to individuals enrolled in the Pre-Existing Condition Insurance Plan (PCIP) program administered directly by HHS beginning with covered services furnished on June 15, 2013. This interim final rule also prohibits facilities and providers who, with respect to dates of service beginning on June 15, 2013, accept payment for most covered services furnished to an enrollee in the federally-administered PCIP from charging the enrollee an amount greater than the enrollee's out-of-pocket cost for the covered service as calculated by the plan. The PCIP program was established under Section 1101 of Title I of the Patient Protection and Affordable Care Act (Affordable Care Act).

DATES: Effective date: This interim final regulation is effective on June 15, 2013.

Comment date: To be assured consideration, written comments must be received at one of the addresses provided below, no later than 5 p.m. on **[OFR--insert date 60 days after date of publication in the Federal Register]**. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

ADDRESSES: In commenting, please refer to file code CMS-9995-IFC3. 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-9995-IFC3,
P.O. Box 8010,
Baltimore, MD 21244-8010

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

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

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-9995-IFC3,
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) 786-4492 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.

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.

FOR FURTHER INFORMATION CONTACT:

Kevin Simpson, Centers for Medicare & Medicaid Services, Department of Health and Human Services, (410) 786-0017.

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act, (Pub. L. 111–148) was enacted on March 23, 2010; the Health Care and Education Reconciliation Act of 2010 (Reconciliation Act), (Pub. L. 111–152) was enacted on March 30, 2010 (collectively, “Affordable Care Act”). Section 1101 of the Affordable Care Act directs the Secretary of Health and Human Services (HHS) to establish, either directly or through contracts with states or nonprofit private entities, a temporary high risk health insurance pool program to provide access to affordable health insurance coverage to eligible uninsured individuals with pre-existing conditions. A number of states elected to contract with HHS to establish and administer a high risk pool using PCIP funds. HHS directly established and administers a high risk pool in the remaining states and the District of Columbia.

(Hereafter, we generally refer to this program as the Pre-Existing Condition Insurance Plan program, or the PCIP program. We refer to the PCIP program administered by HHS as the “federally-administered PCIP” or the “Plan” and a PCIP program administered by a state or its designated entity as a “state-based PCIP.”) The PCIP program is intended to provide health insurance coverage to eligible uninsured individuals with pre-existing conditions until 2014. Beginning in 2014, most health insurance issuers will be required to offer coverage to all individuals, regardless of pre-existing conditions, pursuant to section 2704 of the Public Health Service Act. Eligible individuals will be able to obtain health insurance coverage either by enrolling in a qualified health plan offered through the new Health Insurance Exchanges (also called Marketplaces) established under section 1311 or 1321 of the Affordable Care Act, or by enrolling in health insurance coverage offered in the individual or group market outside of the Exchanges.

As a temporary bridge to the provisions that go into effect beginning in 2014, the PCIP program was designed to provide coverage to eligible individuals who have been locked out of the insurance market due to their health status. Since enrollment began in July 2010, the PCIP program has experienced significant and sustained growth, enrolling more than 135,000 otherwise uninsured individuals with pre-existing conditions. Many PCIP enrollees have serious health conditions that require immediate and ongoing medical treatment including severe or life threatening conditions such as cancer. In 2012, the average annual claims cost paid per enrollee was \$32,108. This cost per enrollee exceeds even that of state high risk pools that predate the Affordable Care Act for several reasons. Like other high risk pools, PCIP enrollees are limited to people that were previously considered uninsurable due to high expected claims cost. In contrast to many state high risk pools, PCIP enrollees also do not experience any waiting periods or pre-existing condition exclusions upon enrollment in the program.

The combined effect of the number of individuals enrolled in the program, particularly very sick individuals, their high utilization of covered services, and the statutory limitations on enrollee cost-sharing (which limits the maximum amount an enrollee pays out-of-pocket for covered services to \$6,250 in 2013) has led to a situation where the overall cost of the PCIP program is higher than originally projected. While the actuarial estimates that HHS relies on to manage the program fluctuate as new claims data is received and processed, given the current enrollment projections and the current rate of claims payment, the aggregate amount needed for the payment of the expenses of the PCIP program is estimated to exceed the amount of remaining funding appropriated by Congress to pay for such expenses until the statutory end to the program in 2014, unless we implement the policy changes being announced in this interim final rule.

We have already taken measures to contain costs, with the intent of sustaining the program until 2014. In May of 2012, the federally-administered PCIP ceased paying referral fees to agents and brokers in connection with enrolled individuals they had referred to the program and began requiring that applications for enrollment include documentation showing that the individual had been denied health insurance coverage due to the existence of a pre-existing condition. On August 1, 2012, the federally-administered PCIP switched provider networks, reducing both its negotiated and out-of-network payment rates to providers. This network change was followed by a targeted effort to negotiate additional discounts from in-network inpatient facilities that were treating a large number of PCIP enrollees. Additionally in 2012, the federally-administered PCIP limited the specialty drug benefit such that the plan would only cover specialty drugs dispensed by in-network pharmacies.

Beginning January 1, 2013, the federally-administered PCIP implemented additional cost containment measures, including-- (1) the elimination of two of three

former plan options in favor of a single plan option; (2) an increase in the maximum out-of-pocket limit from \$4,000 to \$6,250 for in-network services; and (3) an increase in coinsurance, once the deductible has been met, from 20 percent to 30 percent of the plan allowance for in-network covered services. Furthermore, on February 15, 2013, the federally-administered PCIP suspended its acceptance of new enrollment applications until further notice.

State-based PCIPs suspended their acceptance of new enrollment applications received after March 2, 2013. Additionally, a number of state-based PCIPs have taken measures to constrain costs in their programs, for example, by renegotiating their facility and physician reimbursement rates or by setting their payment rates at levels similar to the rates paid by Medicare. Lastly, in May 2013 HHS began negotiations with state-based PCIPs on a final program contract, with a period of performance running from June 1, 2013 through December 31, 2013. The contract HHS will offer to state-based PCIPs will be a cost reimbursement contract up to, but not exceeding, the funding obligated in the contract.

Based on estimates, HHS believes it is prudent and necessary to make additional adjustments in the federally-administered PCIP with respect to payment rates for covered services in order to ensure that there is sufficient funding available to provide coverage to currently enrolled individuals until the program ends in 2014.

II. Provisions of the Interim Final Rule

This interim final rule specifies that we are using our authority under section 1101(g)(2) of the Affordable Care Act to set the payment rates for covered services in the federally-administered PCIP for dates of service beginning on June 15, 2013. As explained below, with the exception of covered services furnished under the prescription drug, organ/tissue transplant, dialysis and durable medical equipment benefits, covered

services furnished to enrollees in the federally-administered PCIP program will be paid at-- (1) 100 percent of Medicare payment rates, or (2) where Medicare payment rates cannot be implemented by the federally-administered PCIP, 50 percent of billed charges or a rate generated pricing methodology using a relative value scale which is generally based on the difficulty, time, work, risk and resources of the service. (Hereafter, we generally refer to this pricing methodology as “relative value scale” pricing.) These rates will become the new plan allowances for the covered services, with the Plan being responsible for reimbursing the facility or a provider for a portion and the enrollee being responsible for reimbursing the facility or provider for the remainder, as calculated by the Plan using the current cost sharing rules described in the Plan brochure.

Furthermore, to protect enrollees in the federally-administered PCIP from having to shoulder potentially significant costs that could be shifted to them as a result of this new payment policy, we are also adopting a policy that prohibits any facility or provider who, with respect to dates of service beginning on June 15, 2013, accepts payment for a covered service provided to an enrollee in the federally-administered PCIP (excepting only the four benefit categories discussed below) from charging the enrollee an amount greater than the enrollee’s out-of-pocket cost for the covered service as calculated by the Plan based on the plan allowance for the covered service. In other words, as a condition of accepting payment for most covered services, facilities and providers will be prohibited from “balance billing” enrollees in the federally-administered PCIP for the difference between the plan allowance for those covered services and the charge for the covered service that they might otherwise bill to a patient who is not a federally-administered PCIP enrollee.

Presented below is a discussion of the specific regulatory provisions set forth in this interim final rule.

A. Insufficient Funds (§152.35(c))

Section 1101(g)(2) of the Affordable Care Act states that “[i]f the Secretary 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, the Secretary shall make such adjustments as are necessary to eliminate such deficit.” We have codified this provision at 45 CFR 152.35(b).

Since enrollment began in July 2010, the PCIP program has experienced significant and sustained growth, providing affordable health care insurance to more than 135,000 of the sickest and most vulnerable uninsured individuals with pre-existing conditions. As a result, claims paid by the PCIP program are, on average, 2.5 times higher than claims paid by state high risk pools that predate the PCIP program. Based on enrollment and claims data, current HHS estimates indicate that the aggregate amount needed to pay for PCIP program expenses may be greater than the remaining funding appropriated by Congress to pay for such expenses until coverage under the program ends in 2014. Thus, to ensure that there is sufficient funding to pay for the expenses of the PCIP program until 2014, as directed by the statute, we are adding a new §152.35(c) to our regulations. This new section states that with the exception of covered services furnished under the prescription drug, organ/tissue transplant, dialysis and durable medical equipment benefits, the payment rates for covered services in the federally-administered PCIP with dates of service beginning June 15, 2013 will be paid at-- (1) 100 percent of Medicare payment rates; or (2) where Medicare payment rates cannot be implemented by the federally-administered PCIP, 50 percent of billed charges or a rate using relative value scale pricing methodology. For purposes of implementing this interim final rule, we presume that (for covered services paid at 50 percent of billed charges) a facility or provider’s billed charge will be reasonable. Such charges are

subject to review. The benefit and premium provisions codified at 45 CFR part 152 Subpart D will not change. In addition, as the new payment rates will become the new plan allowances for the covered services, we note that the Plan will be responsible for reimbursing the facility or a provider for a portion of these rates, and the enrollee will be responsible for reimbursing the facility or provider for the remainder, as calculated by the Plan using the current cost sharing rules described in the Plan brochure.

HHS chose to index the new payment rates that will apply to most covered services to the Medicare payment rate because Medicare rates are widely accepted, familiar, and publicly available. Since Medicare payment rates are well known by facilities and providers, we believe using a rate indexed to Medicare best informs them of what the payment rate for most covered services will be. Based on enrollment and claims data, current HHS estimates indicate that implementing a payment rate that is 100% percent of Medicare will allow us to ensure that there is sufficient funding to pay for the claims and administrative expenses of the PCIP program until coverage under the program ends in 2014.

Since the federally-administered PCIP utilizes a third party administrator to administer the Plan, there are a few instances where Medicare rates cannot serve as the basis for indexing the new Plan rates. The payment rate for these covered services will be 50 percent of billed charges or calculated using a relative value scale pricing methodology. We have chosen to adopt a different payment rate in such instances to ensure that the services currently covered under the Plan can continue to be covered by the federally-administered PCIP while also addressing the need to further contain program costs. These rates were chosen because the federally-administered PCIP can immediately operationalize them. Given the short remaining life of the program, and the limited number of covered services to which these payment rates would apply, we

believe, it would be inefficient and too costly for HHS to operationalize other payment rates that could be applied to these covered services. We note that a facility or provider will be able to contact the federally-administered PCIP directly to determine the plan allowance for one of these covered services before providing the service to a federally-administered PCIP enrollee. Below, we discuss the specific covered services for which payment will be 50 percent of billed charges or a rate generated using a relative value scale pricing methodology.

To the extent to which these covered services are non-pharmaceutical services, the payment rate will be calculated using a the relative value scale payment methodology that uses a relative value scale generally based on the difficulty, time, work, risk and resources of the service. For pharmaceutical services other than those administered under the current Plan prescription drug benefit, the relative value scale payment methodology is similar to the pricing methodology used for Medicare Part B drugs based on published acquisition costs or average wholesale price for pharmaceuticals as published in the Red Book by RJ Health Systems, Thomson Reuters. In these cases the plan allowance will be based on the above described relative value scale pricing methodology and subject to the prohibition on balance billing (discussed below). If no Medicare payment rate or relative value scale pricing methodology is available, the federally-administered PCIP will apply the 50 percent of billed charges payment rate. In these cases, the plan allowance is also subject to the prohibition on balance billing (discussed below).

Other instances where covered services will be paid at 50 percent of billed charges are-- (1) professional services where there are no comparable CPT codes; (2) facility based services where the facility does not participate in Medicare and therefore has no Medicare ID; (3) facility-based services where Medicare rates are not yet available or not yet incorporated into the payment software; (4) facility-based services provided in

a free-standing facility for skilled nursing facilities, long-term acute care facilities, rehabilitation facilities, mental health and substance abuse facilities; (5) facility-based services where all data elements required to calculate the Medicare payment rate are not provided; (6) facility-based services for home health providers (UB billers only); and (7) covered services that are not covered by Medicare. In these cases the plan allowance will be based on 50 percent of billed charges and subject to the prohibition on balance billing (discussed below). Enrollees will, however, remain responsible for paying any applicable cost-sharing amounts, as calculated by the Plan.

We are adopting these new payment rates for the federally-administered PCIP based on current enrollment projections and the current rate of claims payment. If these enrollment and claims projections change after this interim final rule goes into effect, HHS may opt, through future rulemaking, to change the payment rate.

Given the changes we have already made to the prescription drug benefit in the federally-administered PCIP as previously discussed, we believe that establishing new payment rates for prescription drugs is not administratively feasible or cost effective. Therefore, the current plan allowances that apply to the prescription drug benefit in the federally-administered PCIP will not be affected by this interim final rule and will continue to apply. Similarly, we will not apply the new payment rates to covered services furnished under the organ/tissue transplant benefit to ensure that enrollees continue to have access to the federally-administered PCIP's network of transplant centers of excellence, which we believe will lead to fewer complications, shorter lengths of stay, fewer readmissions, better health outcomes, and lower costs. Accordingly, the current plan allowances for covered services furnished under the organ/tissue transplant benefit will remain the same. Also, we will not apply a new payment rate to the dialysis services provided under the diagnostic and treatment services benefit because we are

unable to operationalize a Medicare payment rate. We believe that the current negotiated rates with dialysis providers result in payments that are likely to be less than 50 percent of billed charges. Therefore, we believe maintaining our current in-network payment rate for this service is more competitive than if we were to implement a new payment rate at 50 percent of the billed charge. Finally, we will not apply the new payment rates to covered services furnished under the durable medical equipment benefit, which currently is provided to enrollees in the federally-administered PCIP on an in-network basis only. We believe that the rates currently paid for durable medical equipment are at least as competitive as Medicare payment rates.

This interim final rule establishes new payment rates for most covered services furnished in the federally-administered PCIP. The federally-administered PCIP is administered directly by HHS. We note that HHS can implement this interim final rule quickly and efficiently. The state-based PCIPs have previously indicated to HHS that they are unable to implement new facility and provider rates quickly. Therefore, we have taken the contracting strategy outlined herein with state-based PCIPs.

B. Premiums and cost-sharing (§152.21(c))

Section 1101(c)(2)(D) of the Affordable Care Act requires that a PCIP program established under this section meet “any other requirements determined appropriate” by the Secretary. We are using this authority to adopt a new requirement for the federally-administered PCIP that conditions a facility or provider’s acceptance of the new payment rates discussed above for most covered services on the facility or provider’s agreement not to balance bill the enrollee for an amount greater than the cost-sharing amount calculated by the Plan.

Balance billing is a term generally used to describe the practice of billing a patient for the difference between the plan allowance for a covered service and the amount that

the facility or provider would otherwise charge for the service. Although the federally-administered PCIP currently contracts with a network of facilities and providers that have agreed not to balance bill, it may not be able to sustain that contractual arrangement as it currently exists, or otherwise enter into new contracts with networks that will accept as payment in full the payment rates we are adopting in this interim final rule. Thus, the federally-administered PCIP may operate without a network for most covered services, and the corresponding protection against balance billing that has, to date, been available to enrollees who choose to use network facilities and providers.

Without such protection, enrollees in the federally-administered PCIP could become liable to pay significant out-of-pocket costs for many covered services. We understand that facility and provider charges will often be higher than the rates we are setting in this interim final rule. Allowing this financial liability to transfer to the enrollee could leave federally-administered PCIP enrollees no better off than they would have been if they had no PCIP coverage, and runs counter to the entire PCIP concept, which is to provide affordable health insurance coverage to those who need it most. Also, we believe that the payment rates we are setting in this interim final rule are still better than the alternative, which is leaving facilities and providers with the possibility of having to decide whether to furnish uncompensated care.

Accordingly, to safeguard federally-administered PCIP enrollees from experiencing potentially significant increases in their out-of-pocket costs due to balance billing, we are adding a new §152.21(c) to our regulations. Beginning with June 15, 2013 dates of service, this new section requires all facilities and providers that accept payment from the federally-administered PCIP for furnishing a covered service to an enrollee (with the exception of covered services furnished under the prescription drug, organ/tissue transplant, dialysis and durable medical equipment benefits) to accept as

payment in full the plan allowance for the covered service, which includes the cost-sharing amount calculated by the Plan for the covered service. With respect to these covered services, facilities or providers may not bill the enrollee for an amount greater than the amount determined by the Plan to be the enrollee's cost-sharing amount for the covered service.

The prohibition on balance billing will not apply to covered services furnished under the prescription drug, organ/tissue transplant, dialysis and durable medical equipment benefits because, as explained above, covered services furnished under these benefits will continued to be paid at the existing in-network payment rates. We do not apply the balance billing prohibition to these covered services because it is our desire to encourage federally-administered enrollees to continue to seek treatment for these covered services from in network facilities and providers for the cost-containment reasons described above.

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 and the 60-Day Delay in the Effective Date

Under the Administrative Procedure Act (APA) (5 U.S.C. 551, et seq.), a notice of proposed rulemaking and an opportunity for public comment are generally required before promulgation of a regulation. We also ordinarily provide a 60-day delay in the effective date of the provisions of a rule in accordance with the APA (5 U.S.C. 553(d)),

which requires a 30-day delayed effective date and the Congressional Review Act (5 U.S.C. 801(a)(3)), which requires a 60-day delayed effective date for major rules.

However, this procedure can be waived if the agency, for good cause, finds that notice and public comment and delay in effective date are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. 5 U.S.C. 553(d)(3); 5 U.S.C. 808(2).

HHS has determined that issuing this regulation in proposed form, such that it would not become effective until after public comments are submitted, considered, and responded to in a final rule, would be impracticable and contrary to the public interest. The PCIP program is intended to provide benefits to eligible uninsured individuals with pre-existing conditions until 2014. However, the funding available to pay claims against, and the administrative costs of, the PCIP program is limited by statute, and HHS estimates that, at the current rate of expenditure, the aggregate amount needed for the payment of program expenses may be greater than the amount of remaining funding appropriated by the Congress to pay such expenses. Moreover, for individuals with pre-existing conditions enrolled in the PCIP program, the program may be their only available source of health coverage before prohibitions on discrimination by health insurance issuers based on pre-existing conditions go into effect in January 2014. It is critical to the continued sustainability of the program that the new payment rates go into effect as soon as operationally possible. A delay in the implementation of the new reimbursement rates beyond June 15, 2013 would risk program funds being exhausted prior to 2014.

We also believe that it would be impracticable and contrary to the public interest to delay the implementation of a policy that prohibits facilities and providers from billing federally-administered PCIP enrollees for the difference between the plan allowance for

most covered services and the amount they would otherwise charge for the covered services. The PCIP program is a program of last resort for individuals who, because of their pre-existing conditions, are either denied coverage in the individual market altogether, or can only obtain coverage that excludes their pre-existing condition (often at substantially higher premium rates than those paid by other individuals). The Affordable Care Act not only makes coverage available to these individuals until the more general pre-existing condition protections become available in 2014, but does so at a lower cost than they otherwise would likely have to pay if they did not have health coverage. Furthermore, if the network currently in place in the federally-administered PCIP became unavailable as a result of the new payment rates being set in this interim final rule, we are concerned that the balance billed charges could cause irreparable financial harm to enrollees and deter them from seeking services at all. Because we want not only to preserve the program benefit structure as intended by the Congress, but also meet the needs of enrollees in the federally-administered PCIP who expect that their out-of-pocket costs will be limited, we believe that it would be impracticable and contrary to the public interest to create a situation in which these enrollees are either deterred from seeking covered benefits under the program altogether, or are forced to pay substantially higher out-of-pocket costs than they would have otherwise had to pay absent our adoption of a policy prohibiting balance billing in this interim final rule.

For the foregoing reasons, we find good cause to waive the notice of proposed rulemaking and 60-day delay in the effective date and to issue this final rule on an interim basis.

We are providing a 60-day public comment period, and this regulation will be effective on June 15, 2013.

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.

We are not soliciting public comment on these issues addressed in this interim final rule because we are not making changes to the information collections associated with this program, which are covered under OMB Control Number OMB-0938-1100.

VI. Regulatory Impact Analysis

A. Summary and Need for Regulatory Action

Section 1101 of Title I of the Affordable Care Act requires that the Secretary establish, either directly or through contracts with states or nonprofit private entities, a temporary high risk pool program to provide affordable health insurance benefits to eligible uninsured individuals with pre-existing conditions. The Affordable Care Act envisions that this program will provide coverage to eligible uninsured individuals with preexisting conditions until 2014, when these individuals will begin to have access to a broader range of affordable health coverage options, including qualified health plans offered through new Health Insurance Exchanges established under sections 1311 or 1321 of the Affordable Care Act. An interim final rule published July 10, 2010 (75 FR 45014) set forth and addressed 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. This interim final rule sets forth new payment rates that apply to most covered services with dates of service beginning June 15, 2013, in the federally-administered PCIP. Payment rates for covered services -- with the exception of covered services furnished under the prescription drug, organ/tissue transplant, dialysis and durable medical equipment

benefits will be--(1) 100 percent of Medicare payment rates; or (2) where Medicare payment rates cannot be implemented by the federally-administered PCIP, 50 percent of billed charges or a rate generated using a relative value scale pricing methodology. This interim final rule is an exercise of our authority to make program changes that we have determined are prudent and necessary to ensure that there is sufficient funding to pay for program expenses until 2014.

Additionally, to protect federally-administered PCIP enrollees from potentially becoming financially liable to pay significant costs for covered services as an unintended consequence of this interim final rule, we are adopting a policy that prohibits facilities and providers from billing an enrollee for the difference between the plan allowance for a covered service (with the exception of covered services furnished under the prescription drug, organ/tissue transplant, dialysis and durable medical equipment benefits) and the amount that they would otherwise charge for the covered service. In other words, facilities and providers that furnish covered services to federally-administered PCIP enrollees must accept, as payment in full, the plan allowance for most of those covered services (as determined by the Plan) and not bill the enrollee for an amount greater than the cost-sharing amount that the federally-administered PCIP has calculated for the covered service.

Executive Order 12866 explicitly requires agencies to take account of “distributive impacts” and “equity.” Setting the federally-administered PCIP payment rates applicable to most covered services with dates of service beginning on June 15, 2013, is prudent and necessary to ensure the PCIP program continues to provide benefits to enrolled individuals with pre-existing conditions who cannot obtain health coverage in the existing insurance market until 2014, when these individuals will begin to have access to a broader range of coverage options, including qualified health plans

offered through new health insurance marketplaces established under sections 1311 or 1321 of the Affordable Care Act. Based on enrollment and claims data, current HHS estimates indicate that the aggregate amount needed to pay for PCIP expenses may be greater than the remaining funding appropriated by Congress to pay for such expenses until coverage under the program ends in 2014. Therefore, it is critical that we set the new payment rates and prohibit balance billing under the federally-administered PCIP as soon as operationally possible so that we can ensure that funding remains available to provide benefits to PCIP enrollees until 2014 and enrollees are protected from potentially significant out-of-pocket costs.

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 at least 1 year. Accordingly, OMB has reviewed this rule pursuant to the Executive Order.

HHS provides an assessment of the potential costs, benefits, and transfers associated with this interim final regulation, summarized in the following table.

Table 1.1 Accounting Table

Benefits
Qualitative: The reduction in per-claim costs paid by the federally-administered Pre-Existing Condition Insurance Plan will help to ensure that the PCIP program can continue providing benefits to current enrollees who were previously denied health coverage due to their pre-existing condition. Facilities and providers serving enrollees in the Plan will continue to receive payment for such care, rather than risk receiving no payment for such care should they choose to continue treating the enrollee and PCIP program funding is exhausted prior to 2014.
Costs
Qualitative: Health care facilities and providers will get paid less by the Plan for the same covered services, although given the small number of PCIP enrollees and large amount of uncompensated care that might otherwise be sought by these enrollees, we estimate this cost is minimal.

a. Estimated Number of Affected Entities

This interim final rule sets new payment rates for most covered services in the federally-administered Pre-Existing Condition Insurance Plan (PCIP) furnished beginning on June 15, 2013. It also prohibits a facility or provider from balance billing a federally-administered PCIP enrollee in most circumstances.

Only facilities and providers furnishing covered services to federally-administered PCIP enrollees will be affected by the new payment rates and prohibition on balance billing. Although payment rates will be reduced, facilities and providers choosing to continue to furnish covered services to PCIP enrollees will continue to receive payment, whereas in the absence of PCIP, they might not be able to continue treating the individuals unless they furnish uncompensated care. Although the federally-administered PCIP currently includes an in-network benefit, enrollees are also able to receive treatment

out-of-network, thereby making it difficult to quantify the number of facilities and providers that will be affected by this interim final rule.

b. Benefits

A key premise for the establishment of the PCIP program was that those who are unable to purchase private health insurance coverage due to a pre-existing condition are potentially disadvantaged as a result of both poor health and loss of income. We expect that this interim final regulation will help more than 100,000 current enrollees continue to receive coverage until 2014. According to the 2009 report entitled “Financial and Health Burden of Chronic Conditions Grow,” released by the Center for Studying Health System Change, about 60 percent of the uninsured who have chronic conditions delay care or did not fill a prescription due to cost. Lack of health coverage often leads to significant medical debt, and uncompensated and expensive care at sites such as emergency rooms, shifting these costs in the health system to people with insurance coverage to offset the cost of this uncompensated care. Given these potential consequences of PCIP enrollees losing coverage and becoming uninsured prior to the coverage protections that will go into effect in 2014, this interim final regulation could generate significant benefits to enrolled individuals, for whom it will be possible to continue to be enrolled in the PCIP program. Absent this interim final rule, the PCIP program could exhaust its \$5 billion in appropriated funding before the end of the program in 2014.

The Regulatory Impact Analysis included in the preamble to the 2010 PCIP interim final regulation included a discussion of the PCIP program’s benefit to program-eligible individuals, as compared to the absence of the program. This interim final rule better ensures the continued existence of the program until 2014, as an alternative to the absence of the program during that time period. Therefore, we refer readers to the discussion of the benefits to program-eligible individuals that appears in the Regulatory

Impact Analysis of the July 30, 2010 interim final regulation (75 FR 45026). These benefits could take the form of reductions in mortality and morbidity, reductions in medical expenditure risk, and increases in worker productivity. Each of these effects is described in that Regulatory Impact Analysis.

c. Costs and Transfers

Under Section 1101 of the Affordable Care Act, HHS is authorized to disperse \$5 billion to pay claims and the administrative costs of the PCIP program that are in excess of premiums collected from enrollees.

There will be administrative costs associated with this interim final rule. The federally-administered PCIP claims processing contractor will incur minimal administrative costs to implement the payment rates required by this regulation to ensure that its systems are properly coded to pay the payment rates established under this interim final rule. This cost will be minimal because the claims processing contractor has an existing system in place to adjust its payment rates to reduce the payment rates to the amount specified.

This interim final rule will not increase or decrease costs to the federal government. The Congress appropriated \$5 billion for the PCIP program, and HHS intends to spend that \$5 billion for PCIP-related costs, although this regulation will change how a portion of the remaining \$5 billion is distributed by spreading funding for the maximum period of time by setting new payment rates in the federally-administered PCIP.

With respect to other parties, we lack data with which to quantify costs associated with this regulation. Setting new payment rates for most covered services under the federally-administered PCIP program gives facilities and providers two choices. One choice is to continue to treat federally-administered PCIP enrollees and accept the

payment rates set by this regulation as payment in full. We acknowledge that facilities and providers would, in general, be paid less to treat PCIP enrollees but we believe such cost is minimal (relative to facilities and providers' annual revenues). In the absence of this regulation, funding for the PCIP program may be exhausted prior to 2014, causing enrollees to seek from the same facilities and providers uncompensated and expensive care. Facilities and providers who furnish covered services to individuals enrolled in the federally-administered PCIP, the anticipated reduction in PCIP revenue per claim will not, in the aggregate, eliminate their overall PCIP revenue. The other choice that facilities and providers have is to no longer treat PCIP enrollees. While we understand that the decision to no longer treat PCIP enrollees is possible, we believe and are hopeful that most facilities and providers will accept the new payment rates established in this interim final rule given the serious health conditions many federally-administered PCIP enrollees have and the prospect that such reduced payment is temporary until 2014 when no one can generally be denied health coverage because of a pre-existing condition. Facilities or providers who choose to not accept the payment rates established in this interim final rule could limit a federally-administered PCIP enrollee's ability to access health care services. However, this same possibility would occur if the PCIP program were to end before 2014. Lastly, because the PCIP program serves such a small population nationwide, and the program is temporary in nature, it is unlikely that a facility or provider's annual revenue would be significantly impacted by continuing to treat PCIP enrollees at the new payment rate. Therefore, we believe that this interim final regulation has minimal cost to such providers and facilities.

d. Conclusion

Under section 1101 of the Affordable Care Act, HHS is authorized to spend \$5 billion for the purpose of funding the PCIP program. Implementing this interim final

regulation, through which HHS is setting payment rates for most covered services under the federally-administered PCIP program to 100 percent of Medicare payment rates, may not impose any substantial financial costs on any parties.

For facilities and providers, the anticipated reduction in PCIP revenue per claim will likely be offset by the cost of uncompensated care in the absence of the PCIP program, a cost that facilities and providers would frequently incur if the PCIP program terminated earlier than 2014, due to funds being exhausted. Therefore, this interim final regulation has, in aggregate, minimal cost to such facilities and providers. By ensuring that coverage continues through the end of the year, when new options become available, the payment rates set forth in this interim final regulation will likely have a significant, positive financial impact on individuals enrolled in the program.

We anticipate that PCIP enrollees, who might otherwise lose their PCIP coverage will benefit from this interim final rule because they will be able to maintain their PCIP coverage. We also anticipate that ensuring the PCIP program's existence through 2014 will reduce the burden on local and state governments to pay health care facilities and providers for uncompensated care and prevent shifting of uncompensated care costs in the health system to people with insurance coverage to offset the cost of such uncompensated care.

VII. Other Sections

Regulatory Alternatives

Under the Executive Order, we must consider alternatives to issuing regulations and alternative regulatory approaches. This interim final rule sets payment rates for covered services in the federally-administered PCIP with dates of service beginning June 15, 2013 to reduce the rate of expenditures in order to eliminate the potential funding deficit estimated to occur in calendar year 2013. While other program modifications, as

previously summarized, have been implemented to contain program costs, no other viable alternatives were identified that could substitute for the changes included in this interim final rule.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies that issue a regulation to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The RFA generally defines a “small entity” as--(1) a proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of “small entity.” The Secretary certifies that this interim final rule 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 certain spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold is approximately \$141 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 (or their designated nonprofit, private entities) chose to contract with HHS to administer PCIP and receive federal funding for

doing so. If they did not choose to administer a PCIP, HHS established a PCIP in the state. Thus, this interim final rule does not impose an unfunded mandate on states.

Enrolled individuals have to pay a premium and other out-of-pocket expenses to maintain their enrollment in a PCIP. However, individuals are free to disenroll based on their evaluation of the costs and benefits of remaining in the program. There is no automatic enrollment and no requirement to enroll or remain enrolled in a PCIP. Thus, this interim final rule does not impose an unfunded mandate on the private sector.

Federalism (Executive Order 13132)

Under the specific provisions of the Affordable Care Act, States or State-delegated non-profit entities are contractors of the HHS in the implementation of the PCIP program. HHS has given those contractors flexibility within the parameters provided by the Affordable Care Act and within the budgetary capacity of the program.

Congressional Review Act

This proposed regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq) and has been transmitted to the Congress and Comptroller General for review.

V. Statutory Authority

This interim final rule is adopted pursuant to the authority contained in section 1101 of the Patient Protection and Affordable Care Act (Pub. L. 111-148).

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, Part 152 as set forth below:

PART 152—PRE-EXISTING CONDITION INSURANCE PLAN PROGRAM

1. The authority citation for Part 152 continues to read as follows:

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

2. Section 152.21 is amended by adding paragraph (c) to read as follows.

§ 152.21--Premiums and cost-sharing.

* * * * *

(c) Prohibition on balance billing in the PCIP administered by HHS. A facility or provider that accepts payment under § 152.35(c)(2) for a covered service furnished to an enrollee may not bill the enrollee for an amount greater than the cost-sharing amount for the covered service calculated by the PCIP.

3. Section 152.35 is amended by adding paragraph (c) to read as follows.

§152.35-- Insufficient funds.

* * * * *

(c) Payment rates for covered services furnished beginning June 15, 2013 to enrollees in the PCIP administered by HHS. (1) Covered services furnished under the prescription drug, organ/tissue transplant, dialysis and durable medical equipment benefits will be paid at the payment rates that are in effect on June 15, 2013.

(2) With respect to all other covered services, the payment rates will be--

(i) 100 percent of Medicare payment rates; or

(ii) Where Medicare payment rates cannot be implemented by the federally-administered PCIP, 50 percent of billed charges or a rate using a relative value scale pricing methodology.

Dated: May 15, 2013

Marilyn Tavenner

Acting Administrator,

Centers for Medicare & Medicaid Services.

Dated: May 16, 2013

Kathleen Sebelius,

Secretary,

Department of Health and Human Services.

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