



PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

September 21, 2010

Jay Angoff  
Director  
Office of Consumer Information and Insurance Oversight  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
Room 445-G  
200 Independence Avenue, S.W.  
Washington, DC 20201

Attention: OCIO—9993—IFC

Dear Mr. Angoff:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments on the “Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes under the Patient Protection and Affordable Care Act (PPACA),” published in the Federal Register on July 23, 2010. PCMA is the national association representing America’s pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 210 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, and Medicare.

PCMA appreciates all the tasks that the Departments of Treasury, Labor, and Health and Human Services must complete to implement PPACA and we value opportunities to comment on the many aspects of regulations to implement the law. PCMA is generally supportive of the Internal Claims and Appeals IFR, but we do have concerns with certain provisions that we address in our detailed comments below.

**Internal Claims and Appeals and External Review Processes, 45 CFR 147.136**

Section 2719 of the Public Health Service Act, as amended by PPACA, requires group health plans and health insurance issuers to adopt the appeals processes set forth in 29 CFR 2560.503-1, promulgated by the Department of Labor, which apply to ERISA plans. The IFR also imposes new requirements in addition to the ERISA requirements and PCMA has significant concerns with three of these requirements.

**1. Twenty-Four Hour Turnaround on Benefit Determinations**

PCMA is concerned that the reduction from 72 hours to 24 hours for notification to claimants of benefit determinations involving urgent care, set forth in Section 147.136(b)(2)(ii)(B), will adversely affect patients by compromising the quality of the review process. In many situations involving prescription drug coverage, the prescribing

physician must be contacted. A 24-hour turnaround will likely disrupt the work flow in physicians' offices and hospital outpatient departments, and it may not be feasible for them to get a response back to the plan or PBM in that timeframe. If a physician cannot be reached to confirm the appropriateness of drug therapy within the 24-hour window, the plan or its PBM may have no choice but to deny the claim, thus inconveniencing the patient and forcing her to initiate additional remedial action.

The reduction in the time for determination of a benefit claim to 24 hours, whether adverse or not, places an inordinate burden on the health plan, the PBMs who service their drug claims, and prescribers, particularly on weekends and across time zones for national plans. The standard for turnaround of urgent claims in all states is greater than 24 hours, and the standard under ERISA is 72 hours. 29 CFR 2560.503-1 (f)(2)(i).

***PCMA Recommendation:** PCMA recommends modification of the IFR to adopt and be consistent with the ERISA standard of 72 hours after receipt of a claim for notice of a benefit determination involving urgent care.*

## **2. Information to Identify Claim on Notice of Adverse Benefit Determination**

The IFR at Section 147.136(b)(2)(ii) also imposes requirements, in addition to those under 29 CFR 2560.503-1, that group health plans and health insurance issuers must meet. Section 147.136(b)(2)(ii)(E) contains several additional notice requirements, one of which specifies that any notice of an adverse benefit determination must include the diagnosis code and the treatment code, along with their corresponding meanings.

Diagnosis and treatment codes are currently *not* provided on prescriptions and are not available for processing prescription drug claims in public and private health benefit plans or under individual insurance policies. If pharmacies and PBMs were required to obtain diagnosis and treatment codes from prescribers or other providers, and add them to the fields used in electronic drug claims processing, considerable delay and administrative burden would ensue. Millions of doctor calls would need to be transacted each day, which would tremendously disrupt work flow in physicians' offices and outpatient clinics and likely require additional staffing to handle all the new calls.

The information currently provided to patients regarding a determination of benefits involving a prescription drug is more than adequate to inform the patient with minimal risk of confusion. A typical notice currently provides the patient with the prescriber's name, the name of the drug, the reason for denial, and the standard applied for the decision. Further, the notice includes the date of request and the date of decision. The diagnosis and treatment codes are not necessary and would not help the subscriber to better identify the drug claim in question.

***PCMA Recommendation:** PCMA requests clarification that the IFR does not require diagnosis and treatment codes for adverse benefit determination notices pertaining to prescription drug benefits.*

### **3. Deemed Exhaustion of Internal Claims and Appeals Processes: No Substantial Compliance or *de minimis* Exceptions**

Section 147.136(b)(2)(ii)(F) states that a plan or issuer which fails to “strictly adhere to all requirements” of paragraph (b)(2) will enable a claimant to be deemed to have exhausted the internal claims and appeals processes and may initiate an external review or pursue remedies under section 502(a) of ERISA or state law. The IFR specifically excludes exceptions for assertions of substantial compliance or *de minimis* errors by the plan or issuer.

Several items of information provided to a claimant are subject to change under State law. For example, South Dakota recently changed its law and now has an external review process: a few weeks ago, it did not. Another example is the IFR’s requirement to disclose the availability of and contact information for State ombudsmen offices: at present, several States have not established such offices. Under the IFR, if a State were to establish such offices on the day a notice were sent to a claimant, and the notice did not contain such information, the plan or issuer would fail to “strictly adhere to all requirements” and the claimant could initiate an external review or pursue other legal remedies.

In order to be in compliance with the proposed strict compliance standard, a plan or issuer would have to conduct daily checks of state laws and regulations to assure that notices correctly reflect the laws in effect on the day the notice is actually sent. PCMA believes the adoption of a strict compliance standard by the IFR is unnecessarily rigid, unduly burdensome, and punitive. PCMA is not aware of industry practices or patterns of abuse that would justify such a strict standard, and neither the rule nor the preamble provide or reference any justification for applying such a standard here.

***PCMA Recommendation:** PCMA urges the Departments to modify the IFR to allow exceptions for substantial compliance and/or *de minimis* errors.*

#### **Applicability Date**

The IFR states that the provisions of 45 CFR 147.136 apply “for plan years (in the individual market, for policy years) beginning on or after September 23, 2010.” For benefit determinations and appeals that are “in process” on that date, PCMA is concerned about changing the rules midstream and what that might mean given the language in the IFR adopting a strict compliance standard. PCMA believes the approach taken by ERISA under 29 CFR 2560.503-1(o) and the coverage of OTC drug products under Flexible Spending Accounts (FSAs), both of which are based on “claims incurred”, would be preferable to the approach adopted by the IFR.

***PCMA Recommendation:** PCMA recommends that the IFR be modified to adopt a “claims incurred” basis for application of the rule to internal claims, appeals and external review processes.*

## **Contact for External Review**

The IFR states in the preamble that plans or issuers must “disclose the availability of, and contact information for, any applicable state office of health insurance consumer assistance or ombudsman”, Fed. Reg., Vol. 75, No. 141, July 23, 2010, pp. 43333-43334, and that the Departments will issue model notices “that could be used to satisfy all the notice requirements under these interim final regulations.” On August 23, DOL, Treasury and HHS jointly released model notices that non-grandfathered plans and health insurance issuers may use to satisfy the requirements for appeals of adverse benefit determinations. However, the model notices do not contain the required contact information, because many states have not established the consumer assistance or ombudsman offices.

Given the IFR’s strict compliance standard, PCMA is concerned about how the plans, issuers, and their PBMs can comply with the disclosure requirement noted above. PCMA believes the Departments should adopt a transition period to allow plans, issuers and their PBMs to periodically update their notices to take into account the availability of state consumer assistance and ombudsman offices as they are established. Further, the adoption of a “good faith compliance” standard for compliance would also facilitate a more orderly transition as the states come into line with the federal standards.

***PCMA Recommendation:** PCMA recommends that the IFR be modified to allow for a transition period for compliance with the requirement to disclose the availability and contact information for state offices of health insurance consumer assistance or ombudsmen.*

## **Continued Coverage Pending Outcome of an Appeal**

Under the subsection that applies to group health plans or group health insurance issuers, Section 147.136(b)(2)(iii), plans and issuers are required to provide continued coverage pending the outcome of an appeal, specifically complying with the requirements of 29 CFR 2560.503-1(f)(2)(ii) which state that “treatments cannot be reduced or terminated without providing advance notice and an opportunity for advance review.” Under the subsection that applies to individual health insurance issuers, Section 147.136(b)(3)(iii), the IFR states such issuers must comply with 29 CFR 2560.503-1(f)(2)(ii) as if they were a group health plan. PCMA is concerned about the application of these requirements in the context of prescription drug benefits.

PCMA believes that if the above-noted provisions are applied to prescription drug benefits, adverse clinical outcomes could ensue. For example, prior authorization requirements for specific drugs are often imposed for safety reasons. We believe the IFR should not be read to require the continued coverage of a specific drug, particularly if that drug is subject to prior authorization for safety reasons. It could be dangerous for the patient to continue taking a product beyond a certain point and coverage should not be extended indefinitely pending the outcome of an appeal.

***PCMA Recommendation:*** *PCMA requests clarification from the Departments regarding the application of the continued coverage requirements to prescription drug benefits and strongly urges the Departments to state that it is not their intent to require extended coverage of specific drug products without appropriate review and oversight.*

We appreciate your consideration of our comments and look forward to continuing to work with the Departments of Treasury, Labor, and Health and Human Services to ensure successful implementation of PPACA.

Sincerely,



Michelle Galvanek  
Vice President, Regulatory Affairs