PCMA
PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

August 27, 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: OCIIO-9994-IFC

Dear Director 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 Under the Patient Protection and Affordable Care Act Relating to Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections," published in the Federal Register on June 28, 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 employers, 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 the health care reform statute and we value opportunities to comment on the many aspects of regulations to implement the law. PCMA is generally supportive of the Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections IFR, but we do have concerns with some aspects of the rules that may affect prescription drug benefits. Our detailed comments appear below.

Section II, B: PHS Act Section 2711, Lifetime and Annual Limits (26 CFR 54.9815-2711T, 29 CFR 2590.715-2711m 45 CFR 147.126)

l. No Lifetime or Annual Limits, Rules of Construction, Section 147.126 (b)
Section 2711 of the Patient Protection and Affordable Care Act (the "Act") generally prohibits group health plans and health insurance issuers offering group or individual health insurance coverage from imposing lifetime or annual limits on the *dollar value* of health benefits. The restrictions on lifetime or annual limits apply to "essential health benefits" as defined in section 1302(b) of the Act, which includes prescription drugs. Subsection (b)(2) allows health plans and health insurance issuers to exclude all benefits for a condition, but states that "if any benefits are provided for a condition, then all the

requirements of this section apply." PCMA is concerned about the interpretation of this section of the rule in the context of health plan limits on certain prescription drug benefits.

Pharmacy benefit managers establish formularies based on the expert review and clinical recommendations of Pharmacy and Therapeutic (P&T) Committees. Most PBMs have a standard formulary, which includes a range of drugs in each therapeutic class necessary for the appropriate drug therapies to be available for physicians to prescribe. Many PBMs and health plans use three-tier formularies, with successively more expensive enrollee cost-sharing for generics, preferred brand, and other brand drugs, respectively. Health plans that use PBM services cover most drugs at some level, although they may impose prior authorization or step-therapy requirements, or other care management requirements that have a sound clinical basis. These tools used by PBMs to manage the use of certain drugs on the formulary are essential for assuring clinically sound drug utilization and for keeping drug benefit costs in line with premiums. Tiered cost-sharing to promote use of cost-effective medications and use of other PBM tools is not considered an annual or lifetime limit under current benefit design and should not be under the final rule, either.

It is important to note that PBMs typically do not know the actual condition for which a drug is prescribed, as no diagnosis information is included with prescriptions. Currently the system for filling a prescription is relatively streamlined: a person submits the prescription to the pharmacy and then picks up the dispensed medication in person or has it delivered by mail. The information on the prescription does not include a diagnosis. In those limited cases where more information is needed, the patient may be directed by the pharmacist to call the plan to obtain prior authorization. Were a health plan and PBM required to show that a drug is being used for a specific diagnosis, the pharmacist would have to call the physician's office every time a patient presented a prescription to obtain the diagnosis, then determine whether the drug is covered for that specific indication, and follow-up with the patient accordingly. In addition to imposing enormous and potentially unworkable new burdens on physicians' offices and pharmacies, delays in patients obtaining their prescriptions could result in many patients simply forgoing needed medication. This would be an unfortunate unintended consequence of the interim final rule.

PCMA urges the Departments not to require pharmacy benefit managers to ensure that a given drug is provided for a particular condition as there is no way to ascertain that. In addition, the Departments should clarify that the mere use of a standard formulary, with its broad list of drugs, does not in and of itself denote benefits provided for a particular condition.

PCMA Recommendation: *PCMA recommends that the Departments take into account that prescriptions do not contain information on the condition for which the drug is being dispensed (i.e., diagnosis) and add clarification to that effect through guidance and in the Final Rule. PCMA also requests clarification in guidance and the Final Rule that prescription drug utilization management tools (e.g, tiered cost-sharing, step therapy, prior authorization, maximum daily dose), which are not based on dollar limits, do not fall within the prohibition on lifetime or annual limits.*

Section II, D: PHS Section 2719A, Patient Protections (26 CFR 54.9815-2719AT, 29 CFR 2590.715-2719A, 45 CFR 147.138)

2. Coverage of Emergency Services, Section 147.138(b)

The Interim Final Rule requires that a plan or health insurance coverage providing emergency services must do so without the individual or health care provider having to obtain prior authorization, without regard to whether the provider furnishing the emergency services is an in-network provider, and without any administrative requirements or limitations on benefits for out-of-network services that are more restrictive than those that apply to in-network providers. Emergency services in the IFR are defined at subsection (4)(ii) to include a medical screening examination and such further medical examination and treatment *available at the hospital* that are required to stabilize the patient. The IFR references Section 1867 of the Social Security Act (42 U.S.C. 1395dd) which codifies the Emergency Medical Treatment and Labor Act ("EMTALA").

PCMA applauds the Departments for limiting the scope of the out-of-network protections to hospital-based emergency medical services. PCMA understands the IFR to limit treatment to that which is provided in the hospital's emergency department, including pharmaceuticals dispensed in the emergency department.

PCMA Recommendation: *PCMA recommends that the Departments clarify that Section 147.138 (b) is limited to those emergency treatments and services (including pharmaceuticals) that are rendered in the hospital's emergency department by emergency department personnel, and does not extend to follow-on treatments or services provided by health professionals or facilities inside or outside the hospital to a patient subsequent to the hospital visit.*

As always, 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 the Patient Protection and Affordable Care Act.

Sincerely,

Michelle Galvanek
Vice President, Regulatory Affairs