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August 27, 2010

Phyllis C. Borzi
Assistant Secretary of Labor
Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N-5653
U.S. Department of Labor
200 Constitution Ave., NW
Washington, DC 20210

Attention: RIN 1210-AB43

Dear Ms. Borzi:

Express Scripts Inc. 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. Express Scripts is one of the largest pharmacy benefit management (PBM) companies in North America, providing PBM services to over 60 million patients. We serve thousands of client groups, including managed-care organizations, insurance carriers, third-party administrators, employers and union-sponsored benefit plans. Express Scripts is headquartered in St. Louis, Missouri.

The following are specific comments about the interim final rule which are concerning to us. We respectfully request that the agency consider these comments as it finalizes this rule. Additionally, we are active members of the Pharmaceutical Care Management Association (PCMA) and incorporate their comments to the IFR by reference.

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)

1. No Lifetime or Annual Limits, Rules of Construction, Section 147.126(b)

Section 2711 of the Patient Protection and Affordable Care 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," including 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." Express Scripts is concerned about the interpretation of this section of the rule in the context of health plan limits on certain prescription drug benefits.

Express Scripts establishes our formularies based on the expert advice and review of our Pharmacy and Therapeutics Committee. The process is clinically driven, not cost driven. From their recommendations, we develop standard formularies for prescription drug coverage which include a range of drugs in each therapeutic class necessary for the appropriate drug therapies.

Further, Express Scripts typically does not know the actual condition for which a drug is prescribed. We urge the Departments not to require pharmacy benefit managers to ensure that a given drug is provided for a particular condition. The Departments should clarify that the mere use of a standard formulary, with its broad list of drugs, does not in and of itself mean that the plan sponsor provides benefits for a particular condition.

The current system for filling a prescription is highly automated. The current electronic or written prescription is not equipped to contain a diagnosis—particularly when a physician may prescribe medications, as appropriate in their professional judgment, which may not always coincide with a medication's FDA-approved labeling. In the 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 to obtain the diagnosis, and then determine whether the drug is covered for that specific indication and follow-up with the patient accordingly. This would place a costly administrative burden on physician offices, pharmacies and patients. It could revert much of the electronic processing back to a less-efficient, manual claims' processing system. An unintended consequence of such a process would be delays in patients being able to obtain their prescriptions and could result in several patients simply forgoing needed medication.

Express Scripts recommends *that the Departments recognize and clarify in the final rule that prescriptions do not contain diagnosis information. Additionally, we request that the Departments state that the mere use of a standard formulary does not mean that a plan sponsor provides benefits for a particular condition. Finally, we ask that the Departments recognize that pharmacy benefit managers' traditional management tools (use of formularies, step therapy, quantity limits, prior authorization, etc.) that 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 issuers that provide emergency services must do so without the individual or health care provider having to obtain prior

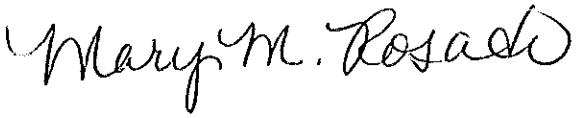
authorization, without regard to whether the provider furnishing the emergency services is an in-network provider, and without any administrative requirements or limitations on benefits for out-of-network services that are more restrictive than those that apply to in-network providers. Emergency services 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).

Express Scripts appreciates the Departments for limiting the scope of the out-of-network protections to the well-established EMTALA provisions of hospital-based emergency medical services. We understand the IFR to limit treatment to that which is provided in the emergency department of a hospital, including pharmaceuticals dispensed in the emergency department.

Express Scripts recommends *that the Departments clarify that Section 147.138(b) is in fact limited to those emergency treatments and services (including pharmaceuticals as necessary) that are rendered in the hospital emergency department 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 emergency department.*

In closing, we appreciate the Departments' consideration of our comments. Successful implementation of the Patient Protection and Affordable Care Act is of utmost importance to Express Scripts.

Sincerely,



Mary Rosado
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