FOOD MARKETING INSTITUTE

April 18, 2011

Submitted Electronically

The Honorable Donald M. Berwick
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: Reducing Regulatory Burdens: Dispensing of Diabetes Supplies

Dear Administrator Berwick:

The Food Marketing Institute (FMI) is writing to you today regarding the regulatory burdens our members face in the dispensing of diabetes supplies.

FMI is the national trade association that conducts programs in public affairs, food safety, research, education and industry relations on behalf of its 1,500 member companies – food retailers and wholesalers – in the United States and around the world. FMI's members in the United States operate approximately 26,000 retail food stores and 14,000 pharmacies. Their combined annual sales volume of $680 billion represents three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms, and independent supermarkets. Our international membership includes 200 companies from more than 50 countries. FMI's associate members include the supplier partners of its retail and wholesale members.

On January 18, 2011, President Obama issued Executive Order 13563 which stated that our nation's regulatory system must "identify and use . . . the least burdensome tools for achieving regulatory ends."

FMI believes that the Centers for Medicare and Medicaid Services (CMS) must address the enormous burdens pharmacies face related to the dispensing of blood-glucose test strips and lancets. The burdens are not only very costly for pharmacies to manage; they are also harming their customers. The recordkeeping requirements pharmacies face over the dispensing of test strips and lancets are much more significant than the paperwork burdens imposed by private insurers for the very same items. These burdens are unnecessary, and we believe that if CMS follows the recommendations contained within this letter, they will be substantially reduced.

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Background

The required documentation associated with the claims process for test strips and lancets imposes very large burdens on FMI members. These documentation requirements are in Local Coverage Determinations (LCDs). Durable Medical Equipment (DME) Medicare administrative contractors (MACs) establish or adopt LCDs which create utilization guidelines and documentation requirements for test strips and lancets.

The LCDs for all DME MACs state:

> Section 1833(e) of the Social Security Act precludes payment to any provider of services unless 'there has been furnished such information as may be necessary in order to determine the amounts due such provider.' It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available on request.

OIG Report

The Office of Inspector General at HHS recently released a report on high utilization claims for test strips and lancets administered by Noridian Administrative Services, LLC (Noridian), the DME MAC for Jurisdiction D.[1] Of the 100 sampled claims for test strips and/or lancets, only 29 were supported in accordance with Medicare documentation requirements.

Sixty-one percent of the claims were not supported due to a lack of "physical documentation" which included:

- Lacking the specific reason for the additional supplies;
- The actual frequency of testing was not documented on the chart notes; or
- The treating physician's evaluation of the patient's diabetic control within 6 months before ordering the supplies was not noted.

Documentation Issues Hurting Pharmacies and Their Customers

Because of these documentation problems, the provider of testing supplies is being forced into a situation in which the patient will ultimately suffer. DME suppliers—like pharmacies—will have no choice but to request this documentation prior to delivering supplies to the patient. Suppliers may begin to withhold services until such documentation is presented, which could lead to lengthy delays in providing testing supplies to diabetics, patient dissatisfaction, and adverse health consequences.

[1] HHS, OIG, Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets, Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction D (February 2011).

If Medicare's current policy remains, coupled with the continued focus on overutilization auditing, pharmacy and prescribing providers will be quickly overburdened by a significant increase in patient chart notes demands. These paperwork burdens will require the addition of staff on both sides to support the requests for documentation, retrieval, photocopying and shipment of those chart notes to the DME provider, and coordination of records to be ultimately shipped to DME MAC's for review.

Medicare Documentation Burdens Greatly Exceed those of Commercial Insurance Plans

Medicare's policy drastically differs from commercial insurance plans.

Only Medicare requires:

1. That physician chart notes be obtained;

2. An ICD-9 code or narrative diagnosis be obtained (and documented by the supplier and within the prescriber's medical record);

3. That an "insulin-use" statement be obtained (and documented by the supplier and within the prescriber's medical record);

4. That a specific medical reason why the patient needs to test more frequently be documented in the prescriber's medical record;

5. That the physician notate within his/her medical record how long the patient will need to test at this higher frequency;

6. That supplies are 'limited' by insulin use or non-insulin use;

7. That testing logs are required to be maintained and kept by the DME provider;

8. That the over-utilizing Medicare patient must be seen and re-evaluated by the prescriber every 6 months; and,

9. In instances where the DME supply item was delivered directly by the supplier (i.e., retail pharmacy where the patient 'picks-up' the item), the date the beneficiary actually received the items is the date of service on the claim.

Commercial insurance regards the prescription to be the 'medical record' and accepts the upper limits of the testing frequency indicated on the prescription without regard to insulin use.

Recommendations for Reducing Burdens

1. If Medicare wishes to impose limits on the amount of blood supplies, then limits without exception should be implemented. The limits would, presumably, eliminate the need for 'medical records.' Medicare can then just use the prescription or detailed written order. Quantities in excess will not be covered and the patient will be forced to pay out of pocket.

2. Implement a combined "Certificate of Medical Necessity—Prescription" document. Only the prescribing provider would be able to complete the CMN-RX. Understanding that 61% of the issues are prescriber driven, he/she would be financially liable for its content, the DME MAC's may request the document from suppliers. Then, the DME MAC's can request a review of the medical records from the prescriber. If the documentation is inadequate; the prescriber is financially liable.

3. CMS should require all diabetic supplies to be processed on-line via a National Council for Prescription Drug Programs 5.1 processing mechanism. That would eliminate "too early refills" or "duplicative therapies." It would also eliminate a significant amount of administrative costs. All pharmacies have 5.1 connectivity. This proposal would require non-pharmacies to obtain 5.1 connectivity. Alternatively, an even simpler approach would be to roll the products into Medicare Part D and eliminate all the additional regulations imposed with these products that physicians are not complying with today.

Implementing the above recommendations would significantly reduce burdens for pharmacies. We urge CMS to do so.

We appreciate your consideration of this important matter.

Sincerely,

Erik R. Lieberman
Regulatory Counsel

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