DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

SEP 8 2005

The Honorable Charles E. Grassley
Chairman, Committee on Finance
United States Senate
Washington, DC 20510-6200

Dear Mr. Chairman:

Thank you for your August 12, 2005, letter on behalf of the Committee on Finance. You requested that my office conduct an evaluation of the Centers for Medicare & Medicaid Services' (CMS) "Demonstration of Improved Quality of Care for Cancer Patients Undergoing Chemotherapy." I am submitting this preliminary assessment today, as requested. This assessment includes our analysis of the cost of the demonstration based on billing data submitted in the first 6 months of 2005, as well as a discussion of the concerns we have identified to date. My office is continuing its review, and I will provide further analysis to you after the completion of the demonstration.

BACKGROUND AND METHODOLOGY

On January 1, 2005, CMS initiated a 1-year "Demonstration of Improved Quality of Care for Cancer Patients Undergoing Chemotherapy." According to CMS, the purpose of the demonstration is to "assess and provide new support for the quality of care for cancer patients undergoing chemotherapy."[1] Under the demonstration, CMS provides a $130 allowance each time a chemotherapy provider reports on a Medicare patient's levels of nausea and/or vomiting, pain, and fatigue—three conditions commonly experienced as symptoms of cancer or side effects of cancer treatment. To participate in the demonstration, a provider submits a claim to Medicare that includes special billing codes, which CMS created for the demonstration. These codes describe, on a four point scale ("not at all," "a little," "quite a bit," or "very much"), the degree to which the beneficiary has been affected by the three conditions.[2] The demonstration requires no formal enrollment; however, it is limited to chemotherapy providers who are practicing in an office setting and to beneficiary visits at which the provider administers chemotherapy via infusion or push.[3] Since the coinsurance requirement was not waived for this

[1] "Fact Sheet: Demonstration of Improved Quality of Care for Cancer Patients undergoing Chemotherapy." Centers for Medicare & Medicaid Services. November 1, 2004. Retrieved August 26, 2005. http://www.cms.hhs.gov/media/press/release.asp?Counter=1245

[2] CMS based the demonstration's four point scale on the Rotterdam Symptom Checklist, an instrument developed as a patient self-assessment tool for measuring the quality of life of cancer patients. A discussion of the Rotterdam scale and how it should be used can be found in *Northern Centre for Healthcare Research, University of Groningen, The Netherlands, "Measuring the Quality of Life of Cancer Patients with the Rotterdam Symptom Checklist (RCSL): A Manual." 1996.*

[3] In infusion chemotherapy, the provider dilutes the chemotherapy drug in a bag of fluid and then administers this solution into a vein over a specified period of time. In the push technique, the provider uses a syringe to administer the chemotherapy drug directly into a vein.

demonstration, beneficiaries are liable for a 20 percent coinsurance payment, which is routinely required for Part B services (20 percent of $130, or $26 in this case), each time their oncologist bills the demonstration codes. CMS estimates that Medicare and its beneficiaries will spend $300 million for the demonstration in 2005.

To evaluate the cost of the demonstration, we analyzed 2005 Medicare claims data received through June 30, 2005. In its Part B Extract and Summary System (BESS), CMS estimates that claims received through June 30, 2005, represent approximately 41 percent of the claims that will be submitted for services rendered this year. Since providers have up to 1 year after the year in which services are rendered to submit claims, complete data on the demonstration will not be available before December 31, 2006.

In addition to the data analysis, we drew upon several sources for our preliminary assessment of the adequacy of the demonstration's data collection methods. We visited two National Cancer Institute-designated comprehensive cancer centers, where we spoke with researchers and clinicians about chemotherapy and the demonstration. We visited a purposive sample of four oncology practices that have participated heavily in the demonstration and two hospital-based practices that cannot participate in the demonstration but routinely assess their patients' conditions. At these practices, we interviewed physicians, nurses, physician assistants, and office staff. We also reviewed the medical and financial records of 11 Medicare beneficiaries whose oncologists had billed the demonstration codes. We discussed the demonstration with key CMS staff and reviewed relevant documentation from both CMS and oncology associations.

ANALYSIS OF DEMONSTRATION CLAIMS DATA

Cost of the demonstration. Medicare allowed $111 million for the demonstration during the first 6 months of 2005. Oncologists billed the demonstration codes for approximately 76 percent of chemotherapy visits that involved push or infusion during the first 6 months of 2005. At the current rate of claims submission, we estimate that CMS will allow approximately $270 million for the demonstration codes in 2005.

Provider participation. Approximately two-thirds of oncologists who have billed at least one push or infusion chemotherapy service in 2005 have also billed the demonstration codes at least once. Approximately 21 percent of participating providers are billing the demonstration codes every time they bill for push or infusion chemotherapy. We found that oncology practices at which more than 10 Medicare beneficiaries have received push or infusion chemotherapy in the first 6 months of 2005 are more likely, based on a chi-square test, to be participating in the demonstration than those with fewer beneficiaries.

Provider reimbursement. While the median allowance for the demonstration codes among participating providers is $6,540, one physician has received more than $320,000 in demonstration evaluation allowances for the first 6 months of 2005. Another physician, who received approximately $220,000 from the demonstration, typically administers chemotherapy to each patient 5 days a week for 2 weeks and bills for the assessments at each visit. Most of this physician's

patients have 2 weeks off before restarting the chemotherapy cycle, which can continue for several years.

Inappropriate payments. Of the $111 million Medicare allowed for the demonstration codes, $3.6 million was for demonstration codes that were not billed in accordance with project requirements. Most of these invalid billings occurred on a day when no push or infusion chemotherapy service was allowed. The remainder involved situations where the provider submitted codes for only one or two of the conditions in the demonstration, instead of all three as required. On December 30, 2004, CMS instructed carriers to reject all such claims. However, apparently not all carriers are following this instruction consistently. To our knowledge, CMS has not instituted any Common Working File edits for the demonstration codes.

Beneficiary liability. Beneficiary liability for the demonstration codes totaled $22 million during the first 6 months of 2002. The maximum beneficiary liability under the demonstration was $1960 for 76 demonstration assessments, and the median beneficiary liability (for beneficiaries with at least one paid demonstration service) was $147. Oncologists billed the demonstration codes at least once for 150,211 beneficiaries during the first 6 months of 2005—approximately 74 percent of the beneficiaries who had at least one paid infusion or push chemotherapy service.

PRELIMINARY ISSUES AND CONCERNS

Based on our brief review, we have identified the following concerns about the demonstration project. We will explore these issues in more detail in the final evaluation that we will provide the Committee early next year.

Reliability and usefulness of data. Published CMS guidelines state, "We have chosen the four level scale in an effort to provide simply stated choices for the patient. . . . We are not mandating a specific approach to collect the data. In general, the patient will be asked to respond to questions about the degree to which they have been bothered by pain, nausea and/or vomiting, and fatigue symptoms in the past week. The assessment may be taken by the practitioner or by a qualified employee of the office under supervision of the practitioner." In the absence of more specific guidance, oncology practices have implemented different procedures for performing the assessments.

Timeframes. While CMS has instructed its carriers that the assessments should cover symptoms experienced "in the past week," this is not the general procedure among the four participating oncology practices we visited. While some offices are assessing patient symptoms during the prior week, others are assessing symptoms only on the day of chemotherapy. This could potentially introduce considerable measurement error into the data CMS is collecting. For example, one nurse told us if a patient vomited several times in the last week, but was feeling fine on the day of the assessment, she would report the lowest level of nausea and/or vomiting. Based on the same information, another practitioner

could legitimately report the highest level of nausea and/or vomiting, based on the frequency of the patient's symptoms during the prior week.

Data collection methods. From our initial review, it appears that chemotherapy providers do not administer the demonstration assessments in a uniform manner, which can result in the submission of unreliable data. Nurses in the four participating oncology practices that we visited told us they ask patients if they have experienced any nausea and/or vomiting, pain, or fatigue (over an uncertain time period—see previous paragraph). The nurses then interpret the patient's verbal response and assign one of the demonstration codes to the each condition. The nurses generally do not ask patients to rate themselves on the four point scale, nor do they use a standardized script to conduct the interviews.

The instrument upon which CMS based this demonstration is intended as a self-administered paper questionnaire, not as an interview guide. Furthermore, if some practices are using written patient self-assessment forms (as recommended by some national oncology associations), the reliability of the demonstration data is even more questionable (since studies have shown that research subjects consistently offer more positive health assessments to interviewers than to paper questionnaires).[4]

Information collected. The oncologists and researchers to whom we spoke told us that the purpose of conducting routine assessments of chemotherapy patients is to determine suitable interventions or remedies to address patients' symptoms. However, the demonstration does not collect data on the interventions that oncologists use to address nausea and/or vomiting, pain, or fatigue. Our interviewees suggested that omitting this piece of information would limit the usefulness of the demonstration data.

Level of reimbursement. Participating providers can receive $130 in combined Medicare reimbursement and beneficiary coinsurance each time they bill the demonstration codes for a particular patient. During our visits to oncology practices, we observed and were told that nurses generally gather the data used for billing the demonstration codes, and that this takes only a few minutes. For the most part, physician involvement is limited to situations where the patient's condition requires an intervention. While we recognize that reimbursement for services provided under a demonstration need not follow fee schedule rules, it is interesting to note that the average reimbursement during the first 6 months of 2005 for the most complex office visit for an established patient (CPT code 99215) was $118.63. The description of CPT code 99215 states that at least two of the following components are required: a comprehensive history, a comprehensive examination, or medical decisionmaking of the highest complexity—which includes a high risk of complications, morbidity, or mortality, an extensive number

[4] Hochstim, J.R. "A Critical Comparison of Three Stages of Collecting Data from Households." Journal of the American Statistical Association, Volume 62, 976-989, 1967 *and* Biemer, P.P. Health Insurance Finance Agency Evaluation. Unpublished Data. Research Triangle Institute, 1997 *as cited in* Dillman, Don. Mail and Internet Surveys: The Tailored Design Method, 2000.

of diagnoses, and/or highly complex data. Furthermore, according to CMS's 2005 Physician Time File, the practice expense input for CPT code 99215 includes 55 minutes of total physician time. In addition, based on our interviews with CMS and our visits to cancer centers and oncology clinics, it appears that assessing chemotherapy patients' levels of nausea and/or vomiting, pain, and fatigue was already part of the routine care of chemotherapy patients prior to the demonstration.

CONCLUSION

In this letter, we present preliminary issues and concerns associated with the demonstration based on our work to date. As noted, we will provide additional information to you after the demonstration is completed.

If you have any questions about this matter, please contact me or have your staff contact Stuart Wright, Director of External Affairs, at (202) 205-9523.

Sincerely,

Daniel R. Levinson

Daniel R. Levinson
Inspector General