

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**COST AND PERFORMANCE OF
MEDICARE'S 2005 CHEMOTHERAPY
DEMONSTRATION PROJECT**



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OBJECTIVE

To assess the cost and the overall performance of Medicare's 2005 chemotherapy demonstration project.

BACKGROUND

On January 1, 2005, the Centers for Medicare & Medicaid Services (CMS) initiated a 1-year Medicare "Demonstration of Improved Quality of Care for Cancer Patients Undergoing Chemotherapy." According to CMS, the purpose of the demonstration was to "... assess and provide new support for the quality of care for cancer patients undergoing chemotherapy. . . ." CMS provided a \$130 allowance each time a chemotherapy practitioner reported to Medicare, via the claims system, an assessment of a patient's levels of nausea and vomiting, pain, and fatigue—three conditions commonly experienced as symptoms of cancer or side effects of cancer treatment. Beneficiaries were responsible for the usual 20-percent coinsurance (\$26 in this case) each time the codes were billed. CMS estimated that Medicare and beneficiary expenditures for the demonstration would total \$300 million. The demonstration has continued in 2006 in a significantly modified form.

On September 8, 2005, the Office of Inspector General provided Senator Charles E. Grassley, per his request, a preliminary assessment of the demonstration's costs and the adequacy of its data collection methods. We estimated that Medicare and its beneficiaries would pay \$270 million for the demonstration in 2005 and noted that approximately 3 percent of demonstration payments were for services that did not meet program rules. We also reported that participants administered the demonstration assessments inconsistently and that CMS was not collecting information on the interventions used to manage patients' symptoms. Finally, we noted that the demonstration allowance was disproportionate to the amount of effort involved on the part of the practitioners and that assessing symptoms was already part of routine cancer care.

To evaluate the cost of the demonstration, we analyzed demonstration claims received by Medicare through the end of 2005. To produce our overall assessment of the demonstration project, we conducted interviews with CMS staff and reviewed e-mails, meeting notes, and other workpapers CMS sent in response to our request for the entire project file and any supplemental documents related to the

demonstration. We also interviewed staff at four oncology practices to learn how they implemented the demonstration.

FINDINGS

Medicare and its beneficiaries will spend approximately \$275 million on the 2005 chemotherapy demonstration. Medicare is on track to allow approximately \$275 million for the demonstration; beneficiary liability will total approximately \$55 million. Approximately 90 percent of eligible practitioners took part in the demonstration, and 85 percent billed the demonstration codes at least half the time. The median amount allowed per physician was approximately \$23,000, but the top 10 billers were allowed more than \$270,000 each.

Seven percent of demonstration claims did not comply with program rules or were paid incorrectly, resulting in \$17 million in net overpayments. Claims that Medicare carriers paid in error included duplicate billings, paying for the demonstration without concurrent chemotherapy, and paying when the beneficiary did not have a cancer diagnosis.

CMS did not sufficiently define the parameters of the demonstration, leading to inconsistent data collection and incomplete and unreliable data. Because CMS did not mandate a specific approach to collecting the demonstration data, oncology practices implemented inconsistent data collection procedures. We identified numerous anomalies and gaps in the data and collection methods that demonstrate the unreliability and undermine the usefulness of the data.

CONCLUSION

We previously reported that physicians who participated in the demonstration used inconsistent methods and timeframes to assess beneficiaries' symptoms. Our analysis of a full year of demonstration data revealed numerous inconsistencies and anomalies that raise further issues concerning the integrity of the data. Based on these concerns, we conclude that the demonstration data are unreliable.

▶ T A B L E O F C O N T E N T S

EXECUTIVE SUMMARY i

INTRODUCTION 1

FINDINGS 7

 Demonstration to cost \$275 million 7

 Inappropriate payments total \$17 million 9

 Demonstration data inconsistent and unreliable 10

CONCLUSION 13

ACKNOWLEDGMENTS 14

OBJECTIVE

To assess the cost and the overall performance of Medicare’s 2005 chemotherapy demonstration project.

BACKGROUND

2005 Chemotherapy Demonstration Project

On January 1, 2005, the Centers for Medicare & Medicaid Services (CMS) initiated a 1-year Medicare “Demonstration of Improved Quality of Care for Cancer Patients Undergoing Chemotherapy.” CMS first publicly announced the demonstration in a November 15, 2004, final rule that implemented a revised payment methodology for drugs, which was mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (commonly known as the Medicare Modernization Act).¹

CMS cites section 402(a)(1)(B) of the Social Security Act Amendments of 1967 (the Amendments) as the authority under which the demonstration was operated. This section of the Amendments permits the Secretary of the Department of Health and Human Services to conduct demonstrations “. . . to determine whether payments for services other than those for which payment may be made under [Medicare] (and which are incidental to services for which payment may be made under [Medicare]) would, in the judgment of the Secretary, result in more economical provision and more effective utilization of services for which payment may be made. . . .” According to CMS, the purpose of the demonstration project was to “. . . assess and provide new support for the quality of care for cancer patients undergoing chemotherapy. . . .”²

Under the demonstration, CMS provided a \$130 allowance each time a chemotherapy practitioner reported to Medicare an assessment of a patient’s levels of nausea and vomiting, pain, and fatigue—three conditions commonly experienced as symptoms of cancer or side effects of cancer treatment. To participate in the demonstration, physicians

¹ 69 FR 66236.

² CMS. “Fact Sheet: Demonstration of Improved Quality of Care for Cancer Patients Undergoing Chemotherapy.” November 1, 2004. Available online at <http://www.cms.hhs.gov/media/press/release.asp?Counter=1245>. Accessed on August 26, 2005.

submitted claims to Medicare that included special billing codes that CMS created for the demonstration.³ These codes described, on a four-point scale (“not at all,” “a little,” “quite a bit,” or “very much”), the degree to which the beneficiary had been affected by the three conditions.⁴ The demonstration required no formal enrollment; however, it was limited to physicians practicing in an office setting and to beneficiary visits at which the physician administered chemotherapy via infusion or push for a cancer diagnosis.⁵

CMS estimated that Medicare and its beneficiaries would spend \$300 million for the demonstration in 2005. CMS did not waive the Medicare Part B coinsurance requirement for this demonstration. Therefore, beneficiaries were liable for the usual 20-percent coinsurance (\$26 in this case) each time their physician billed the demonstration codes.

CMS regularly carries out demonstration and other research projects, but the chemotherapy demonstration was much larger in scope than is typical. The \$300 million in estimated expenditures greatly exceeds the budgets of other CMS research projects; the next most expensive research project listed in CMS’s Active Projects Report is a \$60 million project with a performance period of 8 years.⁶ Also, while demonstration projects usually are limited geographically to a small number of sites, the 2005 chemotherapy demonstration was open to all physicians and beneficiaries nationwide.

³ Although nonphysician practitioners were eligible to participate in the demonstration, physicians submitted more than 99 percent of paid demonstration claims. Throughout this report we use the term “physician” to mean any provider of Medicare Part B services.

⁴ 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.

⁵ In infusion chemotherapy, the physician 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 physician uses a syringe to administer the chemotherapy drug directly into a vein.

⁶ The Active Project Report inventories research, demonstration, and evaluation projects undertaken by CMS staff or by external entities with CMS support.

Pursuant to CMS Change Request⁷ (CR) 3670, dated December 30, 2004, demonstration claims were payable only if the following conditions were met:

- The physician submitted at least one code each for nausea/vomiting, pain, and fatigue. (If the physician submitted more than one code for a symptom category, carriers were instructed to allow only the highest-level code.)
- The physician billed the demonstration codes for the same date of service as an allowed code for chemotherapy via infusion or push.
- The date of service of the demonstration codes (and, therefore, the chemotherapy administration code) was in 2005.
- The place of service referenced for both the demonstration codes and the chemotherapy administration was “office.”
- The diagnosis code reported and referenced was for cancer.

According to CMS, no further official instructions were provided to carriers about the demonstration.

CMS has contracted with Mathematica Policy Research, a professional evaluation firm, to analyze the demonstration data. According to CMS, beneficiaries at 80 percent of demonstration assessments reported having no nausea/vomiting and those at 70 percent reported having no pain. Fatigue was more variable, with beneficiaries at approximately 30 percent of assessments reporting none, at 40 percent a little, at 20 percent quite a bit, and at the rest very much. Because the levels of nausea/vomiting and pain reported were consistently low, the contract project officer stated that CMS will focus on beneficiaries’ reported levels of fatigue in further analyses. Among other things, CMS plans to correlate the demonstration data with other claims data, such as hospital admissions and emergency department visits.

2006 Demonstration Project

In a final rule dated November 21, 2005, CMS announced that the demonstration would continue in 2006 in a revised and less costly version.⁸ While both versions collect data via the submission of special billing codes, the codes for the 2006 demonstration must be submitted

⁷ CMS uses Change Requests to instruct carriers to implement Medicare policy changes.

⁸ 70 FR 70272.

with particular evaluation and management (E & M) visits, not with chemotherapy administration. The 2006 demonstration requires that participants (1) submit special codes that correspond to the reason for the E & M visit, (2) indicate whether the participant is following clinical guidelines, and (3) describe the current disease state. Medicare will allow \$23 per encounter, and the usual Part B coinsurance requirement applies, meaning beneficiaries are liable for \$4.60 per encounter. Participation in the 2006 demonstration is limited to hematologists, oncologists, hematologist/oncologists, and gynecological oncologists, and participants may only bill the demonstration for beneficiaries who have specific cancer diagnoses that appear on a list enumerated by CMS. The participant (or staff) provides all information used to bill the 2006 demonstration; other than the physician's assessment of the current disease state, no beneficiary data are collected.

Previous Work

On August 12, 2005, Senator Charles E. Grassley, Chairman of the Senate Committee on Finance, sent a letter to Inspector General Daniel R. Levinson expressing concerns about the cost of the chemotherapy demonstration project and whether the data CMS was collecting would contribute to the goal of improving care for cancer patients. Senator Grassley requested that the Office of Inspector General (OIG) provide an assessment of the cost of the demonstration and the adequacy of its data collection methods.

OIG provided an interim assessment to Senator Grassley on September 8, 2005.⁹ In that assessment, we estimated that Medicare and its beneficiaries would pay approximately \$270 million to physicians and that two-thirds of eligible physicians would participate. Some participants had received large payments under the demonstration—as much as \$320,000 in the first 6 months of the demonstration in one case. Approximately 3 percent of the demonstration claims did not meet the requirements of CR 3670, resulting in \$3.6 million in inappropriate expenditures. We also expressed concerns about the reliability and usefulness of the demonstration data because of inconsistency in the ways participants administered the demonstration assessments and because CMS was not collecting information on the interventions physicians used to manage

⁹ The letter is available on the Web site of the Senate Committee on Finance at <http://finance.senate.gov/press/Gpress/2005/prg101305lett.pdf>.

patients' symptoms. Finally, we noted that the demonstration allowance was disproportionate to the amount of effort involved on the part of the participant and that assessing symptoms was already part of routine cancer care.

In its January 2006 report to Congress, the Medicare Payment Advisory Commission (MedPAC) questioned the demonstration's validity and methodology. MedPAC expressed concern that the demonstration:

- did not have appropriate controls,
- was announced and implemented without any period for comments by clinicians and researchers,
- did not impose a uniform data collection process,
- did not gather data over a consistent timeframe, and
- did not collect data on interventions used to alleviate symptoms.

MedPAC also reported that while all oncology practices it visited (in five States) were participating in the demonstration, most oncologists did not believe it would lead to quality improvements for patients or produce any useful research findings. MedPAC concluded that the demonstration was designed to increase payments to oncologists and stated in a recommendation to Congress that “. . . [t]he Secretary should use his demonstration authority to test innovations in the delivery and quality of health care. Demonstrations should not be used as a mechanism to increase payments. . . .”¹⁰

METHODOLOGY

To evaluate the cost of the demonstration and its financial impact on Medicare and its beneficiaries, we analyzed demonstration claims received through the end of 2005. These data, which we received in February 2006, represent approximately 87 percent of the services rendered in 2005. Because Medicare processes claims submitted up to 1 year after the year in which services are rendered, complete data on the demonstration will not be available before December 31, 2006.

¹⁰ Medicare Payment Advisory Commission. "Report to the Congress: Effects of Medicare Payment Changes on Oncology Services." January 2006.

I N T R O D U C T I O N

We combined the qualitative data we collected for our September interim report with data from additional sources to produce our overall assessment of the demonstration project. Previously, we had visited four oncology practices that participated in the demonstration and interviewed staff at each about the methods they used to collect the data. We also interviewed cancer researchers and spoke with CMS staff about the project. For this report, we conducted additional interviews with CMS staff and analyzed the 2005 claims data to identify patterns and issues that warrant further evaluation. We also reviewed work papers that CMS sent in response to our request for the entire project file and any supplemental documents related to the demonstration. The work papers contained internal e-mails, meeting notes, and other work papers from the development and implementation of the demonstration, as well as publicly released information about the demonstration.

Medicare and its beneficiaries will spend approximately \$275 million on the 2005 chemotherapy demonstration

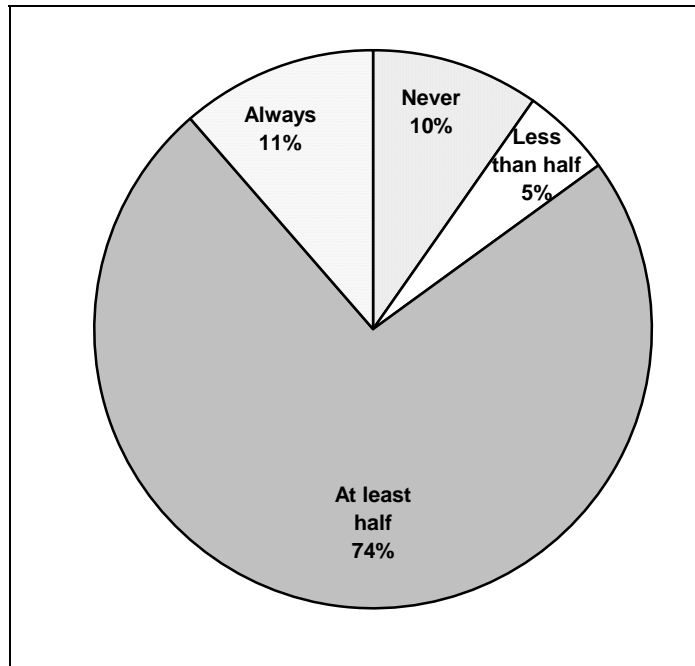
Assuming that the rate of claims submission in the fourth quarter of 2005 is consistent with that of the fourth quarter of prior years,

Medicare will allow approximately \$275 million for the 2005 chemotherapy demonstration.¹¹ Because beneficiaries are responsible for 20-percent coinsurance on demonstration claims, beneficiary liability for the demonstration project will total approximately \$55 million.

Participation in the demonstration was high: approximately 90 percent of eligible physicians took part. Based on a chi-square test, physician practices that had 11 or more beneficiaries receiving chemotherapy for a

cancer diagnosis were more likely to participate than those with fewer eligible patients. Approximately 11 percent of eligible physicians billed and were paid for the demonstration codes at every eligible chemotherapy visit, and 85 percent billed the demonstration codes at least half the time. (See Figure 1.) Overall, Medicare paid for a demonstration assessment at 88 percent of eligible chemotherapy visits.

FIGURE 1:
Percentage of eligible physicians who billed the demonstration codes at a given frequency (e.g, 11 percent of eligible physicians always billed the demonstration codes)



Source: OIG analysis of Medicare claims data, 2006.

The demonstration provided substantial reimbursement to some physicians

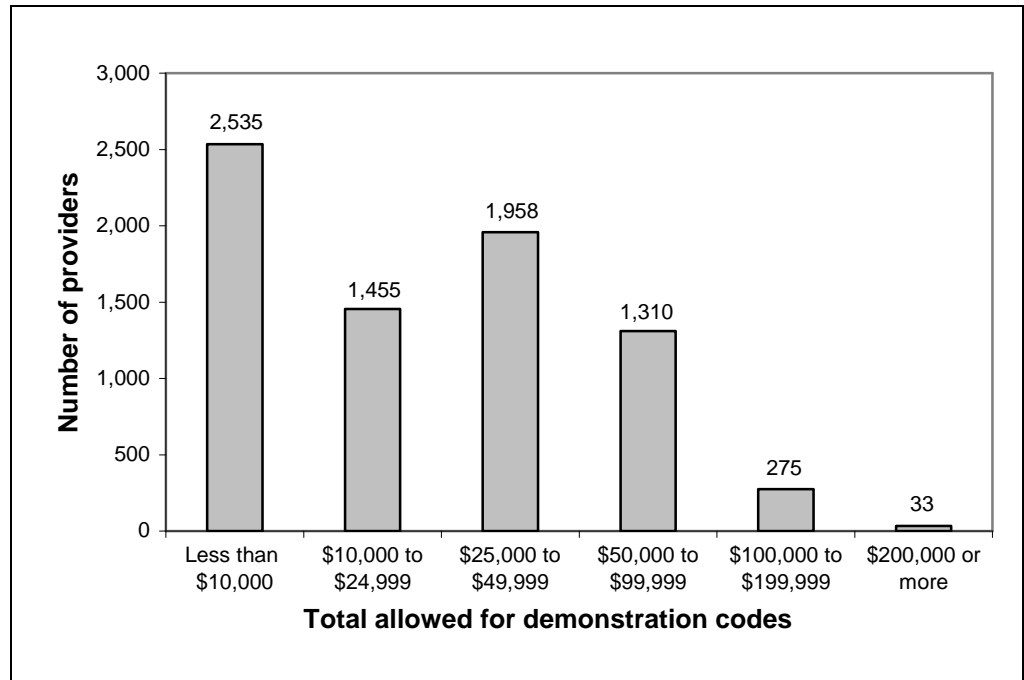
Approximately 7,500 physicians participated in the chemotherapy demonstration. The median amount allowed per physician was approximately \$23,000; however, some physicians were allowed

¹¹ Medicare processes claims submitted up to 1 year after the end of the year in which the service was rendered. As of December 31, 2005, Medicare carriers had allowed 1.8 million assessments performed under the demonstration project, totaling \$239 million in Medicare and beneficiary payments. CMS projects that spending on the demonstration will total \$255 million based on claims received through July 31, 2006.

F I N D I N G S

significantly more than the median. Figure 2 shows the distribution of demonstration payments to individual physicians. Medicare allowed more than \$100,000 each for 308 individual physicians, and the top 10 billers were allowed more than \$270,000 each. The top biller, an oncologist in Florida, was allowed \$625,603 for the demonstration codes. The physician with the second-highest allowed amount for the demonstration, an oncologist in Kansas, was allowed \$507,563. These high billers represent practices that performed substantial amounts of push and infusion chemotherapy and, therefore, had many opportunities to bill for the demonstration.

FIGURE 2:
Distribution of
demonstration
allowances



Source: OIG analysis of Medicare claims data, 2006.

On average, participants in the demonstration were allowed \$529 per patient; for some, the amount was much higher. An oncologist in California had the highest mean allowed amount per patient, \$5,214, of which the patient was responsible for \$1,043. This oncologist typically saw patients daily for 2 weeks, billing the demonstration codes each time. His patients then had 2 weeks off chemotherapy before beginning the cycle again. This oncologist was also among the top 10 billers overall and was allowed a total of \$443,170 for the demonstration codes.

F I N D I N G S

Seven percent of demonstration claims did not comply with demonstration rules or were paid incorrectly, resulting in almost \$17 million in net overpayments

As shown in Table 1, 5.3 percent of the assessments allowed under the demonstration did not meet one or more of the requirements of CR 3670, resulting in \$12 million in

inappropriate allowances. According to claims data, in 62 percent of noncompliant assessments, beneficiaries received chemotherapy for conditions other than cancer.¹² In 46 percent, no push or infusion chemotherapy administration code was allowed on the same day as the demonstration codes. Medicare also paid for a relatively small number of assessments for which carriers allowed codes related to only one or two symptoms, instead of the required three, and assessments that took place in a setting other than the physician’s office.

Table 1: Demonstration Payment Errors

Type of Error	Number	Percentage	Allowed Amount
Noncompliance*	94,801	5.3%	\$12,061,947
- No cancer diagnosis	58,891	3.3%	\$7,700,901
- No chemotherapy	43,996	2.4%	\$5,703,925
- Less than 3 codes	8,681	0.5%	\$667,499
- Not in office	116	0.01%	\$14,950
Incorrect Amount	41,758	2.3%	\$4,936,708
- Duplicates	37,397	2.1%	\$4,797,354
- Multiple units	556	0.03%	\$161,847
- Uncertain reason	3,805	0.2%	(\$22,493)
Overlapping	(3,518)	(0.2%)	(\$208,789)
Total	133,041	7.4%	\$16,789,865**

*Numbers in this subcategory sum to more than the subtotal because some demonstration assessments did not comply with more than one requirement.

**Total does not equal sum of subtotals due to rounding.

Source: OIG analysis of Medicare claims data, 2006.

Medicare allowed too great or too small an amount for 2.3 percent of demonstration assessments, yielding an additional \$4.9 million in net overpayments. These mostly consisted of duplicate claims for one or

¹² CMS did not provide a list of diagnosis codes that defined a “cancer patient” for the 2005 demonstration. For this analysis, we considered a beneficiary a “cancer patient” if he or she had any diagnosis in the “Cancer (Neoplasm, by site, malignant)” or “Carcinoma” sections of the “International Classification of Diseases, 9th Revision, Clinical Modification, Volume 2” listed on any claim for chemotherapy administration with a service date in 2005.

more of the demonstration codes. In some cases, participants obtained excess reimbursement—\$5,936.40 for a single demonstration assessment in one case—by entering multiple units for one or more of the demonstration codes associated with a single date of service. We were unable to determine the reason for the miscalculations in the remaining cases, but most involved apparent Medicare underpayments. One carrier accounted for approximately 87 percent of these unexplained payment reductions, and the remainder was almost entirely confined to three additional carriers.

CMS did not sufficiently define the parameters of the demonstration, leading to inconsistent data collection and incomplete and unreliable data

CMS did not mandate a specific approach to collecting the demonstration data. Consequently, as we reported in our September 2005 letter

to Senator Grassley, oncology practices implemented different procedures for collecting the data. Reviewing the full year’s data has not allayed our previous concerns and has provided further evidence that the data are unreliable.

Prior concerns revisited

In our September letter, we expressed concern that participants in the demonstration were not using consistent methods to administer the assessments. Some of the practices we visited were asking patients about their symptoms during the past week, but others reported the data based on how the patients were feeling on the day of chemotherapy. This could 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/vomiting. Based on the same information, another practitioner could legitimately report the highest level of nausea/vomiting, based on the frequency of the patient’s symptoms during the past week.

Furthermore, while nurses in the practices we visited asked patients directly about their experiences and then interpreted them on the four-point scale, some national oncology associations had recommended that their members instead have patients fill out self-assessment forms and use those to bill the demonstration codes. (CMS had instructed that participants or qualified staff members perform the assessments.) Because practitioners used different methods to gather demonstration

data, the reliability of the data was further compromised. Studies have shown that research subjects consistently offer more positive health assessments to interviewers than to paper questionnaires.¹³

Our analysis of the full year's data reinforces our concerns about the timeframes for which participants assessed their patients under the demonstration. As mentioned previously, CMS indicated in CR 3670 that the symptoms were to be assessed over the past week. However, approximately 32 percent of the symptom assessments occurred less than 1 week after the previous chemotherapy administration, meaning that certain days would be "in the last week" for more than one assessment. CMS did not instruct participants on how to report symptoms in these situations and indicated that carriers should pay the claims. Based on our visits to clinics, beneficiaries at these assessments probably were asked about their symptoms since their last visit or on the day of the current visit, not over the last week, raising further questions about the consistency of data collection in the demonstration.

CMS did not require participants to document demonstration assessments and their results in the patient's medical record. Therefore, CMS cannot verify the accuracy of the data. Given that participants did not generally submit demonstration claims immediately after performing an assessment (the median delay was approximately 9 days), not documenting the services could present a significant data integrity concern. This concern is heightened for the 16 percent of demonstration claims submitted separately from the related chemotherapy administration—approximately 31 days later, on average. Although the practices we visited generally documented their patients' symptoms, some assessments were not documented. In the absence of documentation, it is unclear how the participant would have ensured the submitted codes accurately reflected their patients' symptoms.

Lastly, as discussed in the September 8 letter to Senator Grassley, CMS failed to collect information about the interventions physicians use to address nausea/vomiting, pain, and fatigue. The oncologists and

¹³ 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.

researchers to whom we spoke suggested that omitting this information would limit the usefulness of the demonstration data. The American Society of Clinical Oncology has expressed similar concerns.

New concerns surface

The demonstration focused specifically on the symptoms of cancer patients, but the demonstration data may include the experiences of patients who received chemotherapy for other conditions. CMS specified in CR 3670 that, to be eligible for payment, the demonstration codes had to point to a cancer diagnosis. However, CMS did not define a list of valid diagnosis codes for the demonstration, leaving the carriers to create their own lists. According to our analysis, these lists were not consistent. For example, several of the larger carriers allowed no demonstration claims with a diagnosis code corresponding to a chemotherapy encounter (which does not specify the condition for which chemotherapy is being administered), while others allowed up to 6 percent with this diagnosis and 5 smaller carriers allowed more than 15 percent.

According to CMS, the demonstration focused on measuring outcomes in patients undergoing chemotherapy, but 8 percent of the allowed demonstration assessments were conducted on the first day of a course of treatment.¹⁴ Although data from these assessments could serve as a baseline measurement for each patient, the data could not be considered an assessment of the symptoms associated with chemotherapy because, on the first day of treatment, the beneficiary has not yet been given any chemotherapy. CMS has not indicated that “first-day” demonstration data will be treated any differently than data gathered during a course of treatment.

¹⁴ We considered an assessment to be on the first day of a course of treatment if it occurred after at least a 60-day break in chemotherapy billings. Since we only had 2005 data available, we only looked at assessments that occurred on March 1 or later, to account for chemotherapy that may have taken place at the end of 2004.

► C O N C L U S I O N

We previously reported that physicians who participated in the demonstration used inconsistent methods and timeframes to assess beneficiaries' symptoms. Our analysis of a full year of demonstration data revealed numerous inconsistencies and anomalies that raise further issues concerning the integrity of the data. Based on these concerns, we conclude that the demonstration data are unreliable.



A C K N O W L E D G M E N T S

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