Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

Blood Glucose Test Strips:
Inappropriate Medicare Payments

JUNE GIBBS BROWN
Inspector General

JUNE 2000
OEI-03-98-00230

OFFICE OF INSPECTOR GENERAL

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EXECUTIVE SUMMARY

PURPOSE

To assess the appropriateness of Medicare payments for blood glucose test strips by examining critical elements of this Part B benefit, including coverage requirements, supplier information and documentation, and beneficiary utilization.

BACKGROUND

Medicare covers home blood glucose monitors and test strips for beneficiaries who must periodically test their blood sugar levels as part of their diabetes management, regardless of insulin usage. Prior to July 1, 1998, Medicare coverage was restricted to beneficiaries with insulin-treated diabetes. Insulin-treated diabetics usually test their blood glucose levels one or more times a day. Medicare allowances for test strips more than doubled between 1994 and 1997, increasing from about $102 million in 1994 to $220 million in 1997. Allowances exceeded $314 million in 1998.

Suppliers of blood glucose test strips submit claims to the Durable Medical Equipment Regional Carriers (DMERCs) for processing and payment. The supplier must have an order from the beneficiary's physician verifying medical need for blood glucose test strips. Suppliers signify that they have sufficient documentation to establish Medicare coverage of supplies for insulin-treated beneficiaries by appending a ZX modifier to procedure codes representing the supplies furnished.

For this inspection, we collected data from a sample of Medicare beneficiaries with paid claims for blood glucose test strips in 1997 and the medical equipment suppliers who provided the supplies.

FINDINGS

Medicare allowed $79 million for blood glucose test strips with missing or flawed documentation. $33 million in test strip claims had insufficient documentation to support eligibility. An additional $46 million in claims had incomplete orders or no supplier delivery records.

Irregular billing cycles make review of test strip claims difficult. Such irregular cycles can make it difficult for DMERCs to identify overlapping claims, claims without correct supporting documentation, and claims containing excessive amounts of test strips.

RECOMMENDATIONS

To address the vulnerabilities identified in this report, we recommend that the Health Care Financing Administration:

Alert suppliers of the importance of properly completed documentation to support their claims for test strips. This effort should encompass physicians' orders as well as supplier delivery documentation and documentation to support the medical necessity of quantities of test strips greater than 100 per month. In addition, the use and meaning of ZX modifiers should be emphasized. Further, HCFA should periodically review documentation to ensure that it exists and is accurate.

Require suppliers to indicate actual and accurate "start" and "end" dates on claim forms. This action would make it easier for DMERCs to determine the existence of aberrant or potential problems, such as overlapping claims or whether documentation is needed to support more than 100 test strips a month.

Promote supplier concurrence and cooperation with the Office of Inspector General's recently issued document entitled, *Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry*. Suppliers should be encouraged to establish and adhere to the voluntary compliance program to ensure that their operations meet the standards promulgated by the Office of Inspector General along with national health care organizations.

Advise beneficiaries, as part of its outreach service, to report any instances of fraudulent or abusive practices (such as receiving excessive or unrequested deliveries of test strips) involving their home blood glucose monitors, test strips, or related supplies to their DMERCs.

AGENCY COMMENTS

The HCFA concurred with our recommendations. The HCFA noted a number of initiatives that have reduced the incidence of improper payments in recent years. To specifically address our recommendations, HCFA stated that (1) DMERCs will continue to stress the importance of properly completed documentation through a combination of published guidance in supplier manuals and bulletins and supplier education and outreach seminars, (2) in the 2001 "Work Change Process," they will promulgate changes on claims forms to require actual and accurate "start" and "end" dates, (3) they will work with the National Supplier Clearinghouse to include

language in the notifications sent to suppliers awarding them billing numbers to read and adhere to the OIG's *Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry,* and (4) beneficiary outreach efforts will encourage the reporting of abusive supplier practices to the DMERCs. The full text of HCFA's comments can be found in Appendix B.

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INTRODUCTION

PURPOSE

To assess the appropriateness of Medicare payments for blood glucose test strips by examining critical elements of this Part B benefit, including coverage requirements, supplier information and documentation, and beneficiary utilization.

BACKGROUND

Diabetes is an illness characterized by abnormally high glucose or sugar levels in the blood resulting from a deficiency of insulin. Insulin is a hormone produced in the pancreas which regulates blood sugar levels. When insufficient amounts of insulin are produced, serious health complications may result, including heart disease, blindness, kidney failure, and poor circulation in the lower limbs, which could lead to amputation.

There are two main types of diabetes, Type 1 and Type 2. People with Type 1 diabetes are dependent on insulin injections to regulate their blood sugar levels. Generally, Type 1 is diagnosed when patients are children or young adults. Type 2, sometimes called "late onset diabetes" mostly affects adults over age 40. Many Type 2 diabetics can manage their disease with lifestyle changes, such as special diets and exercise. Approximately 16 million people have diabetes in the United States. It is the seventh leading cause of death.

Health care personnel advocate self-monitoring as the key to successful diabetes management. Diabetics are taught to use special devices called blood glucose monitors or meters to test their blood sugar levels. Typically, patients place a tiny amount of fingertip blood on a test or reagent strip which produces a numeric read-out when inserted into the monitor. Depending on the results of the read-out, patients can adjust their insulin dosages or contact their physicians for further instructions. Patients usually test their glucose levels in this manner one or more times a day.

Medicare Coverage of Home Blood Glucose Monitors and Test Strips

Title XVIII of the Social Security Act prescribes coverage requirements under Part B of the Medicare program. Part B covers services and items including durable medical equipment (DME). Claims for home blood glucose monitors and test strips are covered under Part B within the DME benefit. Suppliers submit claims for reimbursement to

DME regional carriers (DMERCs). The four DMERCs process all Medicare claims for prosthetics, orthotics, medical supplies, and other DME. They are under contract with the Health Care Financing Administration (HCFA), the agency which administers the Medicare program.

A blood glucose monitor and the supplies needed to use it effectively are covered if the beneficiary meets these requirements: 1) the patient is under a physician's care for diabetes; 2) the glucose monitor and related accessories and supplies have been ordered by the patient's treating physician; 3) the patient (or patient's caregiver) has been trained to use the required equipment in an appropriate manner; and 4) the equipment is designed for home rather than clinical use.

Medicare Payment Policies and Expenditures

Prior to July 1, 1998, Medicare coverage for home blood glucose monitors and test strips was restricted to beneficiaries with Type 1, or insulin-treated diabetes. Medicare expanded coverage on that date to beneficiaries with Type 2, or non-insulin treated diabetes. Medicare allowances for test strips more than doubled between 1994 and 1997, increasing from about $102 million in 1994 to $220 million in 1997. Allowances exceeded $314 million in 1998.

Medicare reimburses suppliers for test strips based on monthly fee schedule allowances which vary by State. During 1997, the base period of our review, monthly fee schedule allowances for test strips ranged between $34.69 and $40.81 for a box of 50 strips. Effective January 1, 1998, fee schedule amounts were reduced 10 percent to between $31.22 and $36.73 for 50 strips.

Medical Documentation

The supplier must have documentation from the beneficiary's physician verifying medical need for diabetic testing supplies. For diabetic supplies furnished in 1997, such documentation may be an order or prescription which has been signed and dated by the ordering physician. This document (hereinafter referred to as an "order" in this report) must contain a statement indicating that the patient is a diabetic and is being treated with insulin injections. The supplier must indicate on the claim that the order is on file by appending the modifier "ZX" for each supply provided. The ZX modifier may only be used when these requirements are met. The actual order does not have to be submitted with the claim. In addition, when billing for quantities greater than those described as the usual replacement frequency (100 test strips a month), the claim must include documentation supporting the medical necessity for the higher amount. (These documentation requirements were modified when coverage was expanded effective July 1, 1998.)

The DMERCs have requested that suppliers note on the claim if they are billing for more than one month's supplies. However, there is no limit on the number of months of test strips a supplier can bill for at one time.

The HCFA issued a memorandum in December 1998 entitled, "Durable Medical Equipment Carrier (DMERC) Billing Procedures." The HCFA stated that claims involving supplies provided periodically, such as test strips, should not be submitted more frequently than monthly. By limiting the billing to a 30-day cycle, HCFA indicated the program would save extensive program dollars and would simplify the review process at the same time.

Medicare also requires suppliers to maintain detailed records of items furnished to beneficiaries, including brand name, model number, quantity, and delivery dates. Suppliers are required to retain evidence of the delivery of DME items, such as copies of receipts and pick-up slips. This documentation may be requested by the DMERCs to verify delivery of the items.

In June 1999, the Office of Inspector General issued a document entitled, *Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry.* This document can be located on the World Wide Web at http://www.hhs.gov/progorg/oig/modcomp/cpgfinl.htm. The *Guidance*, which was prepared in consultation with health care trade organizations, was designed to promote a higher level of ethical and legal conduct among providers of medical equipment and supplies. The *Guidance* details specific problems which we encountered in our inspection, such as the improper use of ZX modifiers and delivering and billing for supplies without a physician's order.

METHODOLOGY

Sampling

We first selected a simple random sample of 555 Medicare beneficiaries with paid claims for blood glucose test strips in 1997. The beneficiaries were selected from a 1 percent DME claims file developed from HCFA's National Claims History File. We defined our sample population as those patients whose claims for test strips averaged $50 per month or more. In order to compute point estimates and confidence intervals for inappropriate and questionable claims, we treated the beneficiary sample as a single-stage cluster sample in which each of the beneficiaries was a cluster and their 1997 claims were the unit of analysis. Estimates were made only for the universe of beneficiaries with claims averaging $50 a month or more.

We then checked current Medicare records to ascertain if any sample beneficiaries were shown as deceased. We removed these beneficiaries from the sample. In addition, we removed beneficiaries from the sample whose test strips were provided by suppliers under investigation. The remaining sample consisted of 472 Medicare beneficiaries. In all, 310 different suppliers had submitted 2,184 claims for Medicare reimbursement for these beneficiaries. Since many of the 310 suppliers had provided test strips for multiple beneficiaries, our unique supplier-beneficiary combination totaled 540.

Data Collection and Analysis

Beneficiary information. We collected information from beneficiaries via telephone interviews. Questions related to beneficiaries' medical care and treatment for diabetes, frequency of blood sugar testing, how supplies were obtained, and supplier marketing practices. We completed telephone interviews with 313 of the 472 beneficiaries, a 66 percent response rate. The interviews were conducted from December 1998 to June 1999.

Supplier information. We mailed 540 survey forms to suppliers, one for each beneficiary for whom a claim was filed. In addition to asking suppliers about the types of equipment and supplies provided to beneficiaries, we also included questions about their business and marketing practices. Of the 540 surveys mailed, 469 were completed and returned, an 87 percent response rate. The completed surveys represented 1,902 claims.

We also asked the suppliers to provide pertinent items of documentation, including the physician's order, copies of HCFA-1500 Medicare claim forms submitted for the selected beneficiary in 1997, and documentation indicating the test strips were delivered. Additionally, we asked suppliers to submit any records of contact with the sample beneficiaries in 1997. Although not a HCFA requirement, we felt such information would give us valuable insight into the beneficiary's history of test strip utilization and changing needs. In some cases, suppliers, with our concurrence, substituted comparable documentation if requested information was unavailable.

We reviewed supplier responses to confirm that each piece of requested documentation--particularly the physician order--had been submitted. We examined this documentation to ensure that the orders specified that beneficiaries had insulin-treated diabetes in 1997 and had used test strips to monitor their blood sugar levels. We also examined the documentation to ensure they were completed, signed, and dated by the beneficiaries' treating physicians.

According to Medicare guidelines, orders are considered to be completed timely if they are dated prior to or within 30 days after the first service date. We decided that if multiple orders were submitted, the document which was dated closest or prior to the first date of service to be the controlling document for verification purposes. However, if

that order lacked any of the essential elements to support Medicare coverage requirements, we examined other documents to see if the missing elements were present.

In cases where sample beneficiaries were supplied with more than 100 test strips a month, we reviewed the documentation to ensure that prescribing physicians had validated such quantities of supplies. Initially, however, we reviewed the claims listed in our sample database to determine if we could detect claims requiring documentation supporting more than 100 test strips a month. Our database reflected dates of service for the claims as well as billed dollars which indicated quantities of test strips supplied. For the majority of claims, we could easily determine that the additional documentation was not necessary. For example, many claims were dated approximately 30 days apart and only contained a billing for 100 test strips. For some claims, however, billings indicated supplies of greater than 100 test strips. Further, some claims were submitted every two or three months, or, in certain cases, in time periods of less than 30 days. We determined, therefore, that the only way to confirm whether the additional documentation was needed for these claims was to examine copies of HCFA-1500 claim forms along with physician documentation.

We carefully examined information contained on claim forms, particularly "from" and "to" billing dates and any information representing how many months the strips were provided for. Absent such information, we generally assumed that quantities billed were intended for one month's use.

We compared beneficiary and supplier responses to related questions to detect inconsistencies and questionable practices. In cases where conflicting responses were uncovered, we rechecked beneficiary and supplier responses and pertinent documentation before reaching a determination.

We determined that beneficiaries did not meet Medicare coverage requirements for test strips if physician orders were not provided and no reasonable explanation was supplied, orders were unsigned, did not pertain to the sample service dates, or did not indicate a diagnosis of insulin-treated diabetes.

This study was conducted in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

Medicare allowed $79 million for blood glucose test strips with missing or flawed documentation

$33 million in test strips claims had insufficient documentation to support eligibility

Orders for 25 percent of the sampled claims for blood glucose test strips failed to establish beneficiaries' eligibility for the supplies. In these cases, we found that physician orders were missing, failed to contain any indication of insulin usage, were unsigned, or did not cover the dates of service billed. We estimate that Medicare allowed $33 million for test strip claims for which supporting documentation failed to establish beneficiaries' entitlement for these supplies. This figure represents the unduplicated total allowances for these claims; more than one of the problems cited above was present in some orders.

Suppliers in our sample appended ZX modifiers to procedure codes on claims for reimbursement even though documentation was missing or deficient. Medicare guidelines stipulate that ZX modifiers are only to be used when all documentation requirements have been met. The actual documentation does not have to be submitted to the DMERCs when the ZX modifier is used. However, use of the ZX modifier means that the supplier is in possession of all the documents needed to fully support the claim.

Eight percent of claims were supported by orders that did not cover the service dates billed. In these instances, the beneficiaries for whom the flawed orders pertained would not be eligible for test strip coverage. Generally, suppliers must have completed orders in their possession before providing supplies to beneficiaries. However, we found instances where orders were dated months, even years, after the beginning dates of service. In all, we received 63 orders which were completed and signed more than 30 days after test strips were initially provided. Lengths of time from the initial supply of test strips to dates of completed orders ranged from 5 weeks to almost 25 months, with a median of more than 4 months.

About 6 percent of claims had missing orders or orders not signed by physicians. Such deficiencies do not meet Medicare eligibility requirements for coverage of blood glucose test strips.

Under the Medicare guidelines in effect for 1997, insulin use was a requirement for coverage and reimbursement of test strips. This requirement was modified when coverage was expanded on July 1, 1998. For our 1997 beneficiary sample, however, we

found that physician orders for 15 percent of claims did not state that beneficiaries used insulin. About half of the $33 million involved beneficiaries who were not eligible for test strips because they were not using insulin. In addition, our beneficiary survey revealed that 9 percent of the sample beneficiaries did not use insulin during 1997.

An additional $46 million in test strips claims had incomplete orders or no supplier delivery records

In addition to documentation problems affecting beneficiaries' eligibility for blood glucose test strips, we found other documentation problems, which included missing or incomplete supplier delivery documentation and orders not sufficiently detailed. While these problems do not prevent beneficiaries from being eligible for the test strips, they do raise questions about beneficiaries' expected utilization regimens, types and quantities of test strips provided, and whether the products were even delivered. These problems represent $46 million in allowances, according to our estimates.

We found 21 percent of claims were supported by orders which were lacking in such basic details as the item being ordered (in this case, test strips), in addition to any information relating to quantity needed, frequency of utilization, or length of need. Some orders even failed to mention the diagnosis. Medicare requires orders to be sufficiently detailed enough to include a complete description regarding what is being ordered as well as the regimen of use. One DMERC instruction states, "If the order is for supplies that will be provided on a periodic basis, the order should include appropriate information on the quantity used, frequency of change, and duration of need."

Many items billed to the DMERCs require a designated form, such as a certificate of medical necessity (CMN) form. However, during the period of our review, no CMN or special form was required for test strips. Suppliers were free to design their own "order" forms, so long as these forms carried the information which Medicare required. As a result, suppliers submitted a variety of forms constituting orders for diabetic testing supplies. Some forms were exhaustively detailed, while others were nothing more than a line or two written on a physician's prescription pad.

Suppliers could not furnish any delivery documentation for 18 percent of claims. Medicare requires suppliers to maintain documentation detailing items furnished to the beneficiary as well as details regarding the delivery of the items. According to one DMERC instruction, "The supplier must also have a detailed record of the items provided to the beneficiary which would include brand name, model number, quantity and the date of delivery. For durable medical equipment, the supplier should retain delivery and pick-up slips. This information must be sent to the DMERCs if requested."

Irregular billing cycles make review of claims for test strips difficult

We found that many suppliers submitted claims for reimbursement at irregular intervals which we believe made DMERC review of claims difficult. Such irregular cycles can make it difficult to identify overlapping claims, claims without correct supporting documentation, and claims containing excessive amounts of test strips.

We found that Medicare does not require billing dates on claim forms to have an ending date for repetitive supplies even though HCFA-1500 claim forms have blocks for a start date and an ending date. Nearly all of the claims in our sample had the same date in both the "from" and "to" fields. Also, claim forms often failed to contain any statement indicating how many months were being supplied. Without this information, it was difficult to determine whether a supply of test strips was meant for one month or multiple months. Adding to this difficulty, we found suppliers frequently billed in intervals ranging from less than 30 days to every 3 months. Around 15 percent of the beneficiaries (n=88) in the original claims sample of 555 obtained or received two or more test strip supplies in time periods under 30 days.

Irregular billing cycles contribute to the problem of overlapping claims, particularly if multiple suppliers are involved. Essentially, overlapping claims present two potential problems: 1) excessive supplies of test strips not ordered by the attending physician, and 2) more than 100 test strips supplied during a 30-day period without physician authorization. For example, one beneficiary received test strips from three different suppliers during an overlapping time period, and wound up with 600 test strips in one month. There was no medical necessity documentation for more than 100 test strips a month.

These irregular billing cycles, coupled with claims having the same "from" and "to" dates, made it difficult to determine whether claims in excess of 100 test strips were intended to cover more than one month and, as a result, whether additional documentation was needed to support the quantity of supplies claimed. However there were cases in which it did seem clear that additional documentation was required. We found 60 sampled claims with billings for more than 100 test strips a month that we believe lacked documentation to support the necessity for such quantities. During the period of our review, suppliers were required to obtain documentation supporting the medical need for quantities exceeding 100 test strips a month, such as a written statement from the ordering physician. In one example, a beneficiary received 500 strips over a 3-month period, despite the fact that the physician order indicated that she only tested 20 times per week. In another case, a supplier provided a beneficiary with 100 test strips on April 3, 1997 and another 100 strips on April 4, 1997. The physician's order did not contain any documentation to support the medical necessity of more than 100 test strips a month.

RECOMMENDATIONS

To address the vulnerabilities identified in this report, we recommend that the Health Care Financing Administration:

Alert suppliers of the importance of properly completed documentation to support their claims for test strips. This effort should encompass physicians' orders as well as supplier delivery documentation and documentation to support the medical necessity of quantities of test strips greater than 100 per month. In addition, the use and meaning of ZX modifiers should be emphasized. Further, HCFA should periodically review documentation to ensure that it exists and is accurate.

Require suppliers to indicate actual and accurate dates on claim forms. This action would make it easier for DMERCs to determine the existence of aberrant or potential problems, such as overlapping claims or whether documentation is needed to support more than 100 test strips a month.

Promote supplier concurrence and cooperation with the Office of Inspector General's *Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry.* Suppliers should be encouraged to establish and adhere to the voluntary compliance program to ensure that their operations meet the standards promulgated by the Office of Inspector General along with national health care organizations.

Advise beneficiaries, as part of its outreach service, to report any instances of fraudulent or abusive practices (such as receiving excessive or unrequested deliveries of test strips) involving their home blood glucose monitors, test strips, or related supplies to their DMERCs.

AGENCY COMMENTS

The HCFA concurred with our recommendations. The HCFA noted a number of initiatives that have reduced the incidence of improper payments in recent years. To specifically address our recommendations, HCFA stated that (1) DMERCs will continue to stress the importance of properly completed documentation through a combination of published guidance in supplier manuals and bulletins and supplier education and outreach seminars, (2) in the 2001 "Work Change Process," they will promulgate changes on claims forms to require actual and accurate "start" and "end" dates, (3) they will work with the National Supplier Clearinghouse to include language in the notifications sent to suppliers awarding them billing numbers to read and adhere to the OIG's *Compliance Program Guidance for the Durable Medical Equipment, Prosthetics,*

Orthotics and Supply Industry, and (4) beneficiary outreach efforts will encourage the reporting of abusive supplier practices to the DMERCs. The full text of HCFA's comments can be found in Appendix B.

OIG RESPONSE

We support HCFA's continuing efforts to reduce the incidence of improper Medicare payments. Although HCFA indicated that our estimate of improper payments was based on an extrapolation from a sample of high use (emphasis added) beneficiaries, we wish to point out that we selected for our sample those patients whose claims averaged at least $50 per month. We do not believe that all of these beneficiaries should be defined as high-use beneficiaries.

APPENDIX A

Estimates And Confidence Intervals

The tables below contain statistical estimates presented in the Findings section of this report. To calculate the point estimates and confidence intervals for the percentage of claims and total Medicare allowances we used the Survey Data Analysis (SUDAAN) software package. These estimates are weighted based on a single-stage cluster sample design. To calculate the point estimates and confidence intervals for the percentage of Medicare beneficiaries we used the SAS software package. These estimates are based on a simple random sample design. All estimates are reported at the 95 percent confidence level. Estimates were made only for the universe of beneficiaries with claims averaging $50 a month or more.

MEDICARE ALLOWED $79 MILLION FOR BLOOD GLUCOSE TEST STRIPS WITH MISSING OR FLAWED DOCUMENTATION

Table 1.

Claims With Missing or Flawed Documentation

	Point Estimate	**95% Confidence Interval**
Total Medicare Allowances in 1997 for Glucose Test Strip Claims With Missing or Flawed Documentation	$78,939,525	$68,015,130 - $89,863,921

Table 2.

Claims Which Failed to Establish Beneficiary Eligibility

	Point Estimate	**95% Confidence Interval**
Percent of Claims Which Failed to Establish Beneficiary Eligibility	24.50%	18.68% - 30.32%
Total Medicare Allowances in 1997 for Glucose Test Strip Claims Which Failed to Establish Beneficiary Eligibility	$33,009,187	$25,402,245 - $40,616,130

APPENDIX A

Table 3.

Claims With Other Documentation Problems

	Point Estimate	95% Confidence Interval
Percent of Claims With Other Documentation Problems	33.77%	27.56% - 39.98%
Total Medicare Allowances in 1997 for Glucose Test Strip Claims With Other Documentation Problems	$45,930,337	$36,682,684 - $55,177,989

Table 4.

Claims With Orders Not Covering the Dates of Service

	Point Estimate	95% Confidence Interval
Percent of Claims With Orders Not Covering the Dates of Service	8.43%	5.57% - 11.29%

Table 5.

Claims With Missing or Unsigned Orders

	Point Estimate	95% Confidence Interval
Percent of Claims With Missing or Unsigned Orders	5.52%	2.68% - 8.36%

Table 6.

Claims With No Documentation of Insulin Use

	Point Estimate	95% Confidence Interval
Percent of Claims With No Documentation of Insulin Use	15.24%	9.67% - 20.80%

APPENDIX A

Table 7.

Beneficiaries Who Said They Did Not Use Insulin in 1997

	Point Estimate	95% Confidence Interval
Percent of Beneficiaries Who Said They Did Not Use Insulin in 1997	9.45%	8.61% - 10.29%

IRREGULAR BILLING CYCLES MAKE REVIEW OF CLAIMS FOR TEST STRIPS DIFFICULT

Table 8.

Claims Without Documentation That Test Strips Were Ordered

	Point Estimate	95% Confidence Interval
Percent of Claims Without Documentation That Test Strips Were Ordered	20.75%	15.56% - 25.94%

Table 9.

Claims Without Delivery Documentation

	Point Estimate	95% Confidence Interval
Percent of Claims Without Delivery Documentation	17.90%	12.63% - 23.17%

APPENDIX B

Health Care Financing Administration Comments

APPENDIX B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

DATE: MAY 16 2000

TO: June Gibbs Brown
Inspector General

FROM: Nancy-Ann Min DeParle
Administrator

SUBJECT: Office of the Inspector General (OIG) Draft Reports: "Blood Glucose Test Strips: Inappropriate Medicare Payments and Marketing to Medicare Beneficiaries," (OEI-03-98-00230 and OEI-03-98-00231)

Thank you for the opportunity to review and comment on the above-referenced reports. Medicare expenditures for glucose strips rose from $102 million in 1994 to $314 million in 1998, but much of this increase can be attributable to the legitimate use of this benefit by eligible diabetics. The OIG estimate of $79 million in improper payments was based on an extrapolation from a sample of high use beneficiaries in 1997 - before many of our current program integrity issues were addressed.

Since 1993, the Clinton Administration has done more than any previous administration to fight waste, fraud, and abuse of the Medicare program, which pays more than $200 billion each year for health care for nearly 40 million beneficiaries. The result is a record series of investigations, indictments, and convictions, as well as new management tools to identify improper payments to health care providers. Medicare has also reduced its improper payment rate sharply from 14 percent 4 years ago to less than 8 percent last year, and we have several more initiatives currently underway that we expect will further reduce inappropriate program payments in this area.

-- The new comprehensive error rate testing program will establish baselines to measure each contractor's progress toward correctly processing and paying its share of the nearly 1 billion Medicare claims filed each year. Medicare will use the results to target efforts to pay correctly for services provided to beneficiaries. The Health Care Financing Administration's (HCFA's) private contractors must ensure that Medicare pays claims correctly, and these new error rates will measure their performance and guide our oversight. The results will help contractors improve the accuracy of their payments and give HCFA a valuable new weapon in our efforts to reduce waste and abuse.

-- HCFA is using private-sector competition to save an average of 17 percent for beneficiaries and the Medicare program on certain durable medical equipment as part of a competitive-bidding demonstration in Polk County, Florida. We are now conducting a second demonstration in the San Antonio region.

-- Each year, HCFA requires the Durable Medical Equipment Regional Carriers (DMERCs) to actively analyze claims data to identify trends and spot possible abusive practices. This data analysis allows the DMERCs to concentrate their medical review efforts on those items which pose the most threat to the Medicare program. Additionally, the DMERCs continuously review each regional medical review policy to assure that the appropriate protections are in place.

HCFA and the private companies that process Medicare claims have taken steps to ensure that Medicare pays reasonable prices for needed medical equipment. Using the inherent reasonableness authority obtained in the Balanced Budget Act of 1997, we have put forth proposals to reduce excessive charges on certain items to save millions of dollars for beneficiaries and the Medicare program. However, Congress last year prohibited us from proceeding with these efforts until after the General Accounting Office issued a report on the issue. We are awaiting the results of that report so that we can move forward on these important efforts.

We appreciate the effort that went into this report and the opportunity to review and comment on the issues raised. We concur with the OIG's recommendations, and our specific comments follow.

OIG Recommendation

HCFA should alert suppliers of the importance of properly completed documentation to support their claims for test strips.

HCFA Response

We concur and have already taken strong steps to address this issue. DMERCs have published explicit guidance in the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) suppliers manual. The manual provides direction to suppliers on how to properly document the need for these supplies and the proper use of the KS and ZX modifiers. DMERCs also publish quarterly supplier bulletins. These bulletins address issues unique to the supplier community in each DMERC region. Each DMERC conducts supplier education and outreach seminars as well. As the DMERCs continue to receive incomplete documentation or improperly coded claims, they will use the tools, as appropriate, to address the issue.

OIG Recommendation
HCFA should require suppliers to indicate actual and accurate dates on claim forms.

HCFA Response
We concur and will take appropriate steps toward eliminating inappropriate payments for blood glucose test strips, especially with regard to requiring actual and accurate "start" and "end" dates on claims forms. We will work to include this in the 2001 "Work Change Process."

OIG Recommendation
HCFA should promote supplier concurrence and cooperation with the OIG's *Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry.*

HCFA Response
We concur. We will work with the National Supplier Clearinghouse to develop language to be included in the letter sent to each supplier upon award of the supplier number. This language will encourage suppliers to read the OIG's compliance guide, as well as urge them to adhere to the guidance.

OIG Recommendation
HCFA should advise beneficiaries, as part of its outreach service, to report any instances of fraudulent or abusive practices (such as receiving excessive or unrequested deliveries of test strips and misleading advertising) involving their home blood glucose monitors, test strips, or related supplies to their DMERCs.

HCFA Response
We concur. Several current initiatives already address this recommendation for all types of medical equipment. The *Medicare and You* handbook will continue to provide general information on preventing, identifying, and reporting potential fraud and abuse. As part of HCFA's outreach efforts, we will be incorporating tips on identifying fraudulent or abusive practices involving beneficiaries' home blood glucose monitors, test strips, or related supplies to their DMERCs into the revised *Medicare Fraud and Abuse* booklet.

HCFA, in conjunction with the National Diabetes Education Program, has developed a brochure regarding the coverage of home blood glucose monitors and equipment. Included in this brochure is a caution to the consumer about receiving supplies through automatic shipment. Specifically, we have advised beneficiaries not to accept supplies

that are automatically sent to them. Rather, they should report this practice to their DMERC. The brochure also contains the contact numbers of all of the DMERCs where additional coverage information may be obtained.

HCFA, in conjunction with the Administration on Aging (AOA), will continue our involvement in the Senior Medicare Patrol Project. The grantees under this program are trained by HCFA's regional offices and Medicare contractors on how to identify deceptive health care practices such as overbilling, overcharging, or providing unnecessary services. In turn, they will educate beneficiaries and their families on how to read their Medicare statements, to protect their Medicare identification numbers and to contact their providers if they have questions about their bills.

In addition, one aspect of the Who Pays You Pay national campaign, in which HCFA partnered with the AOA, the American Association of Retired Persons, the Department of Justice, and the OIG, was designed to instruct beneficiaries on how to review their Medicare Summary Notices (MSNs) more thoroughly in order to identify potentially questionable services. Various messages are printed on the MSNs to alert beneficiaries on ways to help reduce fraud. For instance, beneficiaries are instructed to not sell their Medicare number and to check for accuracy of dates, services, and amounts billed to Medicare. Beneficiaries are instructed to contact their Medicare contractor with questions.

OIG Recommendation

HCFA should issue bulletins reminding suppliers who routinely waive deductibles and/or coinsurance or who engage in misleading advertising practices that they may be in violation of the Medicare and Medicaid anti-kickback law.

HCFA Response

We concur. HCFA is aware of this issue and in early 1998 issued Fraud Alert 98-02 addressing the scheme to help our contractors focus on this area. We will reemphasize this issue with the Medicare fraud information specialists and will devote a portion of the summer 2000 Beneficiary Integrity Conference to discussion of this issue.

In addition, HCFA will address the issue regarding advising suppliers to seek legal counsel if they have questions or concerns regarding waivers of deductibles and/or coinsurance or the propriety of marketing or advertising materials in an upcoming program memorandum regarding kickbacks.

OIG Recommendation

HCFA should remind suppliers that beneficiaries must specifically request new supplies of test strips before they are dispensed.

HCFA Response

We concur and have taken strong steps to address this issue. The DMEPOS suppliers manual clearly states, **"A beneficiary or their caregiver must specifically request refills of glucose monitor supplies before they are dispensed."** As the DMERCs address aberrancies among providers with this issue, they will use the appropriate tools, as mentioned in the above response, to address this.