

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**QUESTIONABLE MEDICARE PAYMENTS
FOR INCONTINENCE SUPPLIES**



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EXECUTIVE SUMMARY

PURPOSE

This report examines trends in allowances and questionable billing practices for incontinence supplies under Medicare Part B between 1990 and 1993.

BACKGROUND

Incontinence is the inability of the body to control urinary and bowel functions. Under the Medicare Part B program, the Health Care Financing Administration (HCFA) will reimburse suppliers that provide incontinence supplies to aid individuals whose incontinence condition "...is of long and indefinite duration." Such reimbursement is provided only as part of Medicare's coverage for prosthetic devices such as catheters and external urinary collection devices. The HCFA will also reimburse for accessories, such as irrigation syringes and sterile saline solution, that aid in the effective and therapeutic use of these devices. Currently, claims are processed by four Durable Medical Equipment Regional Carriers (DMERCs).

We selected claims for a 1 percent sample of beneficiaries who received one of 43 types of supplies for incontinence care. We arrayed the data by type of supplies, carrier, and major suppliers. We then analyzed the statistical information to develop trends. We also applied current and proposed HCFA guidelines for these incontinence supplies in 1993. We focused on two facets of billing: accessories that can only be billed with prosthetic devices; and frequency limitations on prosthetic devices.

FINDINGS

Medicare allowances for incontinence supplies more than doubled in three years despite a drop in the number of beneficiaries using these supplies.

Incontinence allowances rose from \$88 million in 1990 to \$230 million in 1993, an increase of \$142 million. During the same period, the number of beneficiaries receiving incontinence supplies fell from 312,200 to 292,700. Allowances per beneficiary increased from \$282 to \$786.

Four types of incontinence supplies account for almost all the increase in Medicare allowances.

Between 1990 and 1993, Medicare allowances for irrigation syringes, sterile saline irrigation solution, lubricant, and female external urinary collection pouches increased \$129 million. This accounts for 91 percent of the \$142 million total increase.

Questionable billing practices may account for almost half of incontinence allowances in 1993.

Medicare allowed \$107 million in 1993 for supplies whose billing is questionable. Almost \$88 million was paid for incontinence accessories that were not billed in conjunction with a prosthetic device. An additional \$19 million was paid for beneficiaries whose utilization of certain prosthetic devices appears excessive. The allowances were concentrated in one carrier and a small number of suppliers and beneficiaries.

A proposed change in HCFA policy will probably address questionable billing practices.

Inconsistencies and lack of clear utilization guidelines in carrier policies contributed to the large number of questionable incontinence claims paid by Medicare in 1993. A proposed draft policy (to be issued by the four Durable Medical Equipment Regional Carriers) will clarify covered services and provide a mechanism to link incontinence accessory supplies to prosthetic devices.

NEXT STEPS

Incontinence Supplies

In response to the information presented in this report and a companion report, the Office of Inspector General (OIG) plans to:

- o initiate an audit review to examine in more detail payments made for incontinence supplies in order to determine if any overpayments are involved in this area; and
- o launch a national investigation in this area, examining potentially fraudulent practices by specific suppliers of incontinence supplies.

We also support ongoing activity in HCFA and the DMERCs to develop more specific coverage guidelines and educate providers and suppliers about proper billing for such supplies. We hope the information contained in this report is helpful as they complete this activity.

OIG Studies of Other Nursing Home Supplies

The OIG will continue studies and audits related to its major initiative examining services and supplies provided to Medicare beneficiaries residing in nursing facilities. As this report and other OIG work has reflected, the fragmentation of billing for services and supplies provided to residents of nursing homes has created a host of improper incentives for billers to the Medicare program.

"Bundling" of Services

We continue to support HCFA's efforts to pursue a systematic solution to these kinds of problems through a requirement for "bundling" of services in nursing home settings. Under such an approach, the nursing home would be responsible for providing commonly needed services to residents of that facility, rather than allowing for separate billing by suppliers. Such a solution would eliminate the incentives suppliers now have to aggressively seek out patients in nursing homes and market their products inappropriately in those settings. It would also ensure that nursing homes take on appropriate responsibilities for services and supplies delivered to residents in their facilities.

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INTRODUCTION

PURPOSE

This report examines trends in allowances and questionable billing practices for incontinence supplies under Medicare Part B between 1990 and 1993.

BACKGROUND

Medicare Coverage of Incontinence Supplies

Incontinence is the inability of the body to control urinary and bowel functions. Reimbursement for incontinence supplies is included as part of Medicare's coverage for prosthetic devices. According to Medicare Carriers Manual section 2130, "prosthetic devices (other than dental) which replace all or part of an internal body organ (including contiguous tissue), or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ are covered when furnished on a physician's order."

Under the Medicare Part B program, the Health Care Financing Administration (HCFA) will reimburse suppliers that provide incontinence supplies to aid individuals whose incontinence condition "...is of long and indefinite duration." Certain items, such as absorbent undergarments or diapers, are specifically excluded from coverage.

Incontinence supplies include prosthetic devices such as catheters and external urinary collection devices such as pouches or cups. Catheters are flexible, tubular instruments used to control urinary flow. The HCFA will also reimburse accessories that aid in the effective and therapeutic use of these devices. These accessories include items such as drainage bags, irrigation syringes, sterile saline solutions, and lubricants. However, accessories are not covered in the absence of a prosthetic device.

Carrier Processing of Incontinence Supply Claims

In June 1992, HCFA issued a final rule designating four Durable Medical Equipment regional carriers (DMERCs) to process all claims for durable medical equipment, prosthetics, orthotics, and supplies. Effective October 1, 1993, the DMERCs replaced more than 50 area carriers which had previously processed DME claims. The geographical areas formerly serviced by the carriers were phased in under the DMERCs on a staggered basis. Each DMERC issued its own coverage and reimbursement policies that implement Medicare guidelines.

However, for urological supplies, the DMERCs issued a draft of a single national policy in October 1994. In addition to redefining and clarifying some of the definitions used in claims for incontinence and urological supplies, the policy establishes documentation requirements for higher than usual quantities of supplies. The non-

coverage of diapers and similar absorptive pads is emphasized. The policy also reinforces the condition of "permanence" for coverage purposes and stresses that accessories not used in conjunction with covered catheters or external urinary collection devices are not covered.

Medicare Fraud Alert

One DMERC issued a Medicare Fraud Alert in June 1994 describing a supplier scheme involving the marketing of incontinence kits to nursing homes. In this case, the supplier advised nursing home officials that Medicare was paying for the kits under a "pilot program." According to the alert, supplier representatives provide kits containing accessories such as syringes, saline solution, and lubricants, to the nursing home in exchange for beneficiary names and Medicare health insurance claim numbers. The marketing representative then orders bulk quantities of supplies billed under the beneficiaries' claim numbers.

The alert also indicated that the supplier marketing program stated that the beneficiary should be treated three times per day with the contents of the kit. This resulted in a supplier billing Medicare \$1,800 per month per beneficiary in one carrier jurisdiction.

METHODOLOGY

To determine the trends in incontinence allowances, we arrayed payment and utilization data for each incontinence supply. We also analyzed the utilization data for possible questionable billing practices.

We first reviewed each DMERC's coding and coverage guidelines and interviewed DMERC officials to identify 43 codes used to reimburse incontinence supplies. These did not include any "local" codes used by individual carriers. Supplies were segregated into three groups: catheters, external urinary collection devices, and accessories. The HCFA and DMERC officials provided the designation for each billing code.

We selected all services for 43 codes for a 1 percent sample of beneficiaries from the Part B Medicare Annual Data Procedure File for calendar year 1990 and the National Claims History 100% Physician/Supplier Data for calendar years 1991 through 1993. From the 1993 sample of 2,927 beneficiaries, we obtained an additional file for 231 beneficiaries who accounted for 51 percent of all incontinence allowances, beginning with the beneficiary with the highest amount billed. This file contained all Part B services, in addition to incontinence.

From the sample of incontinence services, we calculated Part B Medicare allowed payments, supply frequency, and number of beneficiaries. Allowed payments include both the 80 percent Medicare payment and the 20 percent coinsurance fee paid by beneficiaries. We arrayed the data by billing code, carrier, and major suppliers. We then analyzed the statistical information to determine trends in incontinence

expenditures. We limited our analysis for frequency utilization to the period 1991 through 1993 because frequency reported in 1990 was not comparable to later years.

According to DMERC coding policies, 11 of the 23 billing codes that cover accessories are also used to reimburse ostomy care. We did not include any services for the 11 codes associated with beneficiaries who received only ostomy care. We also did not include services billed under code A4323, "sterile saline irrigation solution," when it was not billed in conjunction with other incontinence supplies. According to DMERC officials, code A4323 may be used in conjunction with other non-incontinence supplies such as enteral nutrition products.

To determine the nature and extent of questionable billing practices, we interviewed DMERC officials including medical directors and fraud control unit personnel. We reviewed coverage and utilization standards for 1) the three Medicare carriers that were among the highest in allowances in 1993, 2) the current DMERCs, and 3) the proposed DMERC national urological standards.

We projected our findings by multiplying sample results by 100. Confidence intervals for our findings are presented in Appendix A.

We applied current and proposed DMERC guidelines to the services billed for the 43 incontinence supplies in 1993. We focused on two facets of billing: 1) accessories that can only be billed with prosthetic devices, such as catheters and external urinary collection devices; and 2) frequency limitations on prosthetic devices. For each practice, we reported Medicare allowances and frequencies above the tolerance guidelines by type of supply, carrier, supplier, and number of beneficiaries receiving supplies.

This report is one of a series of reports concerning Medicare payments for incontinence supplies. *Marketing of Incontinence Supplies (OEI-03-94-00770)*, describes supplier and nursing home practices that can lead to questionable payments and examines issues concerning Medicare beneficiaries' use of incontinence supplies. The third report, *Medicaid Payments for Incontinence Supplies (OEI-03-94-00771)*, will examine how the Medicaid program processes claims for incontinence supplies in 14 States.

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

FINDINGS

MEDICARE ALLOWANCES FOR INCONTINENCE SUPPLIES MORE THAN DOUBLED IN THREE YEARS DESPITE A DROP IN THE NUMBER OF BENEFICIARIES USING THESE SUPPLIES.

Medicare Part B allowances for incontinence supplies rose from \$88 million in 1990 to \$230 million in 1993, an increase of \$142 million. The most significant portion of that increase came in 1993 when allowances increased \$111 million, almost doubling from the previous year. Over the same time period, the number of beneficiaries receiving incontinence supplies has actually decreased. In 1990, 312,200 beneficiaries received incontinence supplies. In 1993, this figure fell to 292,700. Allowances per beneficiary more than doubled from \$282 in 1990 to \$786 in 1993.

Between 1991 and 1993, the number of incontinence supplies paid for by Medicare more than tripled. In 1991, Medicare Part B reimbursed suppliers for 19 million incontinence supplies. In 1992, reimbursed supplies increased to 25 million. In 1993, supplies more than doubled from the previous year to 60 million. The table below provides a summary of incontinence activity between 1990 and 1993.

Table 1. Incontinence Activity: 1990 - 1993

Activity	1990	1991	1992	1993
Allowances	\$88 million	\$108 million	\$119 million	\$230 million
No. of Beneficiaries	312,200	334,300	281,400	292,700
Allowances per Beneficiary	\$282	\$322	\$423	\$786
No. of Supplies	N/A	18.8 million	24.7 million	59.5 million

FOUR TYPES OF INCONTINENCE SUPPLIES ACCOUNT FOR ALMOST ALL THE INCREASE IN MEDICARE ALLOWANCES.

Between 1990 and 1993, Medicare allowances for irrigation syringes (billing code A4322), sterile saline irrigation solutions (A4323), lubricants (A4402), and female external urinary collection pouches (A4328) increased \$129 million. This accounts for 91 percent of the \$142 million increase for all supplies. The table on the next page shows increases in allowances for the four supplies according to their billing code.

Table 2. Increase in Four Supply Codes

Supply	1990 Allowance	1993 Allowance	Increase
Syringe	\$0.7 million	\$43.3 million	\$42.6 million
Saline Solution	\$7.0 million	\$47.0 million	\$40.0 million
Female Pouch	\$0.02 million	\$15.3 million	\$15.3 million
Lubricant	\$0.5 million	\$32.0 million	\$31.5 million
Total Increase			\$129.4 million

Although the total number of incontinence beneficiaries decreased 6 percent between 1990 and 1993, the number of beneficiaries receiving these four supplies showed significant increases. The table below displays the number of beneficiaries served for each of the four supply codes.

Table 3. Number of Beneficiaries Served for Four Supply Codes

Supply	1990	1993	Percentage Increase
Syringe	7,400	62,700	747 percent
Saline Solution	45,300	95,900	112 percent
Female Pouch	600	9,400	1,467 percent
Lubricant	5,700	59,900	951 percent

Allowances for accessories and collection devices rose significantly between 1990 and 1993 while allowances for catheters increased only modestly.

Allowances for accessories rose from \$61 million to \$183 million, an increase of 200 percent. In 1990, only \$198,900 was spent on all external urinary collection devices. By 1993, expenditures skyrocketed to \$16 million, an 8,051 percent increase. In contrast, allowances for catheters grew 15 percent from \$27 million to \$31 million between 1990 and 1993, an annual increase of 5 percent.

The nature of supply allowances has also changed. In 1990, indwelling catheters (A4338), bedside drainage bags (A4357), and irrigation trays (A4320) accounted for almost half of all allowances. By 1993, 53 percent of all allowances were made for irrigation syringes, sterile saline solution, and lubricants.

The rise in supply utilization mirrors the change in allowances. In 1991, Medicare paid for 19 million incontinent supplies. By 1993, this figure had tripled to 60 million. Suppliers were reimbursed for 63,200 external urinary collection devices in 1991 and

2 million in 1993, an increase of 3,410 percent. Female pouches account for almost 95 percent of the external urinary collection devices supplied in 1993. The number of catheters rose from 6 million in 1991 to 7 million in 1993. Intermittent urinary catheters increased 1.5 million but was offset by a decrease in the number of insertion trays, external catheters, and indwelling catheters.

Allowances are concentrated in one carrier and a small number of suppliers and beneficiaries.

One carrier and a small number of suppliers and beneficiaries account for a significant portion of allowances. Florida Blue Shield accounted for 55 percent of all incontinence allowances in 1993, while six carriers made 50 percent of the allowances in 1990. Of the 1 percent sample claims reviewed in 1993, less than 1 percent of all suppliers received total annual payments of \$50,000 or more, accounting for over one-quarter of all payments. In contrast, no supplier received total payments that exceeded \$50,000 in 1990. While 60 percent of the suppliers received total payments of \$100 or less in 1990, the number dropped to 40 percent in 1993. The following table details incontinence payments by supplier between 1990 and 1993.

Table 4. Incontinence Payments Per Supplier

Total Dollars Allowed	1990		1993	
	% of Suppliers	% of Allowances	% of Suppliers	% of Allowances
Under \$100	60.0	3.3	39.3	0.8
\$100-\$199	9.0	2.5	10.9	1.0
\$200-\$499	12.9	8.2	16.9	3.5
\$500-\$999	7.4	10.2	12.2	5.4
\$1,000-\$4,999	8.9	37.0	15.4	19.1
\$5,000-\$9,999	1.1	14.5	2.7	11.7
\$10,000-\$49,000	0.8	24.4	2.2	30.9
\$50,000+	0.0	0.0	0.5	27.5

In 1993, 10.3 percent of beneficiaries received services over \$2,000 and accounted for 57 percent of allowances. In 1990, payments were less concentrated in such large payments. Only 21 percent of allowances were made to beneficiaries who received \$2,000 or more in services. In 1990, 53 percent of beneficiaries received \$100 or less in incontinence supplies, while 33 percent received comparable payments in 1993. The table on the next page details allowances by beneficiary.

Table 5. Incontinence Allowances Per Beneficiary

Total Dollars Allowed	1990		1993	
	% of Beneficiaries	% of Allowances	% of Beneficiaries	% of Allowances
Under \$100	52.5	5.7	32.6	1.7
\$100-\$199	12.2	6.2	12.7	2.3
\$200-\$499	18.9	21.8	19.4	8.2
\$500-\$999	10.5	26.4	15.0	13.3
\$1,000-\$1,999	4.0	18.7	9.9	17.8
\$2,000-\$2,999	1.2	10.9	3.9	12.1
\$3,000-\$3,999	0.5	5.7	1.9	8.5
\$4,000+	0.2	4.6	4.5	36.0

QUESTIONABLE BILLING PRACTICES MAY ACCOUNT FOR ALMOST ONE-HALF OF ALL INCONTINENCE ALLOWANCES IN 1993

Medicare allowed \$107 million in 1993 for supplies related to questionable billing practices. This represents 47 percent of the \$230 million in allowances. About \$88 million was paid for incontinence accessories for beneficiaries who did not receive a prosthetic device. Additional payments of \$19 million were made for certain prosthetic devices that appear to have excessive utilization. These billing practices are concentrated in one carrier, few suppliers, and few beneficiaries.

Accessories billed without prosthetic devices do not meet Medicare guidelines.

In order for Medicare to pay for incontinence accessories the beneficiary must have a prosthetic device such as a catheter or a urinary collection device. However, \$88 million was allowed for accessories that were not billed with a prosthetic device. As shown in the table on the next page, virtually all allowances that did not meet Medicare guidelines were for just three supplies. The supplies were sterile saline solutions, irrigation syringes, and lubricants. In total, these three supplies account for 94 percent of the \$88 million in questionable billings. As a further check, we reviewed Part B services provided to 96 beneficiaries with large Medicare allowances and found that very few beneficiaries received other durable medical equipment for which these supplies would have been appropriate.

Table 6. Accessories Billed Without Catheter or Collection Device

Supply	No. of Supplies	Allowances
Saline Solution	6,467,500	\$29 million
Syringe	10,268,200	\$31 million
Lubricant	11,312,800	\$22 million
Subtotal for three supplies	28,048,500	\$82 million
All Supplies	29,290,400	\$88 million

Utilization for certain prosthetic devices appears excessive.

As much as \$19 million in allowances may have been overpaid if the proposed DMERC utilization standards had applied to certain prosthetic devices in 1993. Over \$11 million in 1993 was allowed for female external urinary collection pouches (A4328) that exceed the proposed DMERC guidelines of one per day. We are aware that at least one supplier was paid for 186 per month, or 6 per day. Another \$8 million was allowed for beneficiaries who received more than one indwelling catheter per month. The proposed DMERC policy calls for no more than one indwelling catheter per month for routine maintenance. Additional catheter changes are covered only if documentation substantiates medical necessity.

Florida Blue Shield accounted for most of the questionable allowances.

Florida Blue Shield accounted for \$78 million (89 percent) of \$88 million in Medicare allowances for accessories not billed in conjunction with a catheter or external urinary collection device. Over 90 percent of the allowances were for just three supplies: irrigation syringes, sterile saline solutions, and lubricants. Almost 70 percent of the allowances for female external urinary collection pouches was also through Florida Blue Shield.

The allowances for the indwelling catheters that exceeded one per month involved numerous carriers. Four carriers accounted for over 40 percent of allowances. The carriers were Pennsylvania Blue Shield (15 percent), Illinois Blue Shield (10 percent), Blue Shield of Greater New York (9 percent), and Nationwide of Ohio (7 percent). The remaining 60 percent was paid by 44 other carriers.

Allowances were concentrated in few suppliers.

Approximately 5 percent of suppliers (19 in the sample of 471) accounted for over three-quarters of the accessories billed without catheters or external urinary collection devices. All but one of these suppliers were paid by Florida Blue Shield.

Ten suppliers in our sample accounted for all payments for female external urinary collection pouches. All but three of the suppliers were paid by Florida Blue Shield. Only 3 of the 11 codes used to reimburse indwelling catheters showed any concentration of allowances for suppliers. For each of these codes, A4311, A4313, and A4315, one supplier received at least two-thirds of all allowances in our sample. The remaining allowances was shared by several suppliers.

Few beneficiaries receive most of the allowances.

A total of 821 beneficiaries (28 percent from the sample of 2,927) received accessories without a prosthetic device. At least 360 of these beneficiaries were billed for irrigation syringes, sterile saline solutions, and lubricants.

All the excessive allowances for female collection pouches were made to 3 percent of beneficiaries sampled. For each of the indwelling catheter codes except A4338, all excessive payments were made to 1 percent to 6 percent of the beneficiaries sampled. However, almost one-third of the beneficiaries in our sample received more than one catheter per month of those billed under A4338.

A PROPOSED CHANGE IN DMERC POLICIES WILL PROBABLY ADDRESS QUESTIONABLE BILLING PRACTICES.

Inconsistencies and the lack of clear utilization guidelines and controls among carriers contributed to the large number of questionable incontinence claims paid by Medicare in 1993. Current DMERC policies, while more consistent, still do not contain clear coverage definitions. A proposed draft DMERC policy further clarifies covered services and provides a mechanism to link incontinence accessory supplies to prosthetic devices.

Previous carrier policies did not contain clear guidance on coverage and appropriate utilization.

We reviewed policies of three carriers which were among the highest in incontinence allowances for 1993 and found that their guidelines differed for the same types of supplies. For example, for one indwelling catheter code, one carrier allowed two per month while another allowed eight. For one supply code, one carrier allowed 4 per day, the second allowed 1 per week, and the third allowed 30 per month. For the female urinary collection device (A4328), an item with a large number of questionable allowances, two carriers had no utilization guidelines and the third allowed four per month.

The carrier with the highest questionable allowances for 1993 had no frequency or utilization controls for any incontinence supplies except for two intermittent catheter codes. Neither this carrier nor the two other carriers had controls to prevent allowances for incontinence supplies when billed without a prosthetic device.

Current policies, while stronger, do not go far enough.

Current DMERC policies categorize the incontinence supplies benefit under coverage of prosthetic devices. For a prosthetic device to be covered, "the physician must certify that the condition resulting in the need for the device is of long and indefinite duration (at least 3 months)."

All four DMERCs have utilization controls for indwelling catheters, limiting the number of catheters to two per month for routine maintenance. Three DMERCs have strengthened coverage policies for lubricant, stating that it can no longer be reimbursed as a separate supply since it is included in catheter insertion trays.

The DMERCs have also adopted a uniform certificate of medical necessity form. This certificate must be filled out, signed, and dated by the ordering physician and kept on file by the supplier.

Not all DMERCs have computer edits or controls in place to ensure that supplier claims conform with DMERC policies. While all four DMERCs have a utilization standard for indwelling catheters, only two have computer edits. Only one DMERC has an on-line edit to check claims for particular supplies to ensure that the certificate of medical necessity adequately supports the use of these supplies.

Even though the DMERC manuals limit payment for supplies to those that are for the effective use of a prosthetic device, DMERCs do not have controls to prevent payment for incontinence supplies when the beneficiary has neither a catheter nor an external urinary collection device. Without these controls, Medicare will continue to pay for incontinence supplies that do not meet Medicare coverage guidelines.

The draft DMERC policy provides uniform coverage and utilization standards that will lead to improved processing of incontinence supply claims.

The proposed DMERC national guidelines on urological supplies will prevent Medicare payment for supplies not used with covered prosthetic devices. As the draft policy clearly states, "urological supplies that are not used with catheters or external urinary collection devices will be denied as noncovered." It provides even more explanation in the case of sterile saline solution and irrigation syringes by maintaining that "irrigation supplies that are used for care of the skin and/or perineum of incontinent patients are not covered."

The new policy requires suppliers to add a modifier to urological supply codes when the supplies are used with a catheter or external urinary collection device. The new ZX modifier, as it is known, would be added to the end of a code submitted on claims for catheters, external urinary collection devices, or supplies required for the effective use of one of these items. The modifier indicates that "specified coverage criteria in the medical policy have been met and documentation is available in the supplier's records."

If this policy is implemented and claims processing controls are created to ensure that required modifiers are used, large numbers of questionable allowances such as those found in 1993 can be avoided. If the policy had been implemented in 1993, Medicare and beneficiaries could have saved as much \$88 million in questionable payments.

The proposed policy provides more explicit definitions of covered items. It clearly defines female urinary collection devices, insertion trays, and anchoring devices. It also lists supplies sometimes paid for previously that will no longer be covered since they are not required for the effective use of incontinence prosthetic devices (e.g. skin barriers and appliance cleaners).

The policy also contains utilization standards for many incontinence supplies. For instance, no more than one indwelling catheter per month will be covered for routine catheter maintenance. The new policy allows only one male external catheter and one female pouch collection device per day. These new utilization standards coupled with computer edits or controls should significantly decrease the number of excessive incontinence supplies billed to Medicare.

NEXT STEPS

Incontinence Supplies

In response to the information presented in this report and a companion report, the Office of Inspector General (OIG) plans to:

- o initiate an audit review to examine in more detail payments made for incontinence supplies in order to determine if any overpayments are involved in this area; and
- o launch a national investigation in this area, examining potentially fraudulent practices by specific suppliers of incontinence supplies.

We also support ongoing activity in HCFA and the DMERCs to develop more specific coverage guidelines and educate providers and suppliers about proper billing for such supplies. We hope the information contained in this report is helpful as they complete this activity.

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"Bundling" of Services

We continue to support HCFA's efforts to pursue a systematic solution to these kinds of problems through a requirement for "bundling" of services in nursing home settings. Under such an approach, the nursing home would be responsible for providing commonly needed services to residents of that facility, rather than allowing for separate billing by suppliers. Such a solution would eliminate the incentives suppliers now have to aggressively seek out patients in nursing homes and market their products inappropriately in those settings. It would also ensure that nursing homes take on appropriate responsibilities for services and supplies delivered to residents in their facilities.

APPENDIX A

CONFIDENCE INTERVALS

We reported our findings by multiplying 100 by the point estimates in our samples. The point estimates represent the total allowance, number of supplies, or number of beneficiaries. The confidence intervals present the range of possible findings at the 95 percent level. The 95 percent confidence level represents approximately two standard deviations from the sample mean. The two standard deviations, or semi-width, is determined by multiplying 1.96 by the standard error of the sample mean. The variance from the point estimate is determined by multiplying the semi-width of by the sample size. The confidence interval is the plus or minus range of the variance from the point estimate.

The 95 percent confidence intervals are presented in the following tables.

Table 1. Incontinence Activity: 1990 - 1993 (p.4)

Year	Allowances		No. of Beneficiaries		Allowance Per Beneficiary	
	95% Confidence Interval	Projected Total	95% Confidence Interval	Projected Total	95% Confidence Interval	Projected Total
1990	+/- \$5,839,100	\$87,969,900	+/- 10,000	312,200	+/- \$19	\$282
1991	+/- \$7,544,939	\$107,504,300	+/- 10,000	334,300	+/- \$23	\$322
1992	+/- \$8,963,442	\$118,970,400	+/- 10,000	281,400	+/- \$32	\$423
1993	+/- \$15,579,562	\$229,949,200	+/- 10,000	292,700	+/- \$53	\$786

Table 2. Increase in Four Supplies Between 1990 and 1993 (p.5)

Supply	Year	95% Confidence Interval	Projected Total
Irrigation Syringe A4322	1990	+/- \$381,600	\$679,700
	1993	+/- \$3,308,200	\$43,271,800
Saline Solution A4323	1990	+/- \$1,365,700	\$7,035,500
	1993	+/- \$4,888,600	\$47,020,200
Female Pouch A4328	1990	+/- \$25,160	\$18,500
	1993	+/- \$2,643,800	\$15,295,200
Lubricant A4402	1990	+/- \$333,100	\$494,100
	1993	+/- \$2,766,300	\$31,958,300

Table 3. Questionable Billing Practices (p.7)

Supply	95% Confidence Interval	Projected Total
Female Pouch	+/- \$3,070,135	\$11,117,300
Indwelling Catheter	+/- \$1,644,595	\$8,156,900
Sub-Total	+/- \$3,450,294	\$19,274,200
Accessories w/o Prosthetic Device	+/- \$10,784,752	\$87,570,500
Total	+/- \$10,574,064	\$106,844,800

Table 4. Saline Solution, Syringe, and Lubricant Billed Without Prosthetic Device (p.8)

Supply		95% Confidence Interval	Projected Total
Saline Solution A4323	No. of Supplies	+/- 1,296,309	6,467,500
	Allowance	+/- \$4,223,731	\$28,708,232
Irrigation Syringe A4322	No. of Supplies	+/- 1,238,503	10,268,200
	Allowance	+/- \$3,688,280	\$30,845,900
Lubricant A4402	No. of Supplies	+/- 1,562,456	11,312,800
	Allowance	+/- \$3,027,888	\$21,914,501

Table 5. Florida Blue Shield Allowance of Accessories Without Prosthetic Device (p.8)

Florida Blue Shield	95% Confidence Interval	Projected Total
	+/- \$9,890,931	\$77,949,800

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**QUESTIONABLE MEDICARE PAYMENTS
FOR INCONTINENCE SUPPLIES**



JUNE GIBBS BROWN
Inspector General

DECEMBER 1994
OEI-03-94-00772

OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services' (HHS) programs as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by three OIG operating components: the Office of Audit Services, the Office of Investigations, and the Office of Evaluation and Inspections. The OIG also informs the Secretary of HHS of program and management problems and recommends courses to correct them.

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EXECUTIVE SUMMARY

PURPOSE

This report examines trends in allowances and questionable billing practices for incontinence supplies under Medicare Part B between 1990 and 1993.

BACKGROUND

Incontinence is the inability of the body to control urinary and bowel functions. Under the Medicare Part B program, the Health Care Financing Administration (HCFA) will reimburse suppliers that provide incontinence supplies to aid individuals whose incontinence condition "...is of long and indefinite duration." Such reimbursement is provided only as part of Medicare's coverage for prosthetic devices such as catheters and external urinary collection devices. The HCFA will also reimburse for accessories, such as irrigation syringes and sterile saline solution, that aid in the effective and therapeutic use of these devices. Currently, claims are processed by four Durable Medical Equipment Regional Carriers (DMERCs).

We selected claims for a 1 percent sample of beneficiaries who received one of 43 types of supplies for incontinence care. We arrayed the data by type of supplies, carrier, and major suppliers. We then analyzed the statistical information to develop trends. We also applied current and proposed HCFA guidelines for these incontinence supplies in 1993. We focused on two facets of billing: accessories that can only be billed with prosthetic devices; and frequency limitations on prosthetic devices.

FINDINGS

Medicare allowances for incontinence supplies more than doubled in three years despite a drop in the number of beneficiaries using these supplies.

Incontinence allowances rose from \$88 million in 1990 to \$230 million in 1993, an increase of \$142 million. During the same period, the number of beneficiaries receiving incontinence supplies fell from 312,200 to 292,700. Allowances per beneficiary increased from \$282 to \$786.

Four types of incontinence supplies account for almost all the increase in Medicare allowances.

Between 1990 and 1993, Medicare allowances for irrigation syringes, sterile saline irrigation solution, lubricant, and female external urinary collection pouches increased \$129 million. This accounts for 91 percent of the \$142 million total increase.

Questionable billing practices may account for almost half of incontinence allowances in 1993.

Medicare allowed \$107 million in 1993 for supplies whose billing is questionable. Almost \$88 million was paid for incontinence accessories that were not billed in conjunction with a prosthetic device. An additional \$19 million was paid for beneficiaries whose utilization of certain prosthetic devices appears excessive. The allowances were concentrated in one carrier and a small number of suppliers and beneficiaries.

A proposed change in HCFA policy will probably address questionable billing practices.

Inconsistencies and lack of clear utilization guidelines in carrier policies contributed to the large number of questionable incontinence claims paid by Medicare in 1993. A proposed draft policy (to be issued by the four Durable Medical Equipment Regional Carriers) will clarify covered services and provide a mechanism to link incontinence accessory supplies to prosthetic devices.

NEXT STEPS

Incontinence Supplies

In response to the information presented in this report and a companion report, the Office of Inspector General (OIG) plans to:

- o initiate an audit review to examine in more detail payments made for incontinence supplies in order to determine if any overpayments are involved in this area; and
- o launch a national investigation in this area, examining potentially fraudulent practices by specific suppliers of incontinence supplies.

We also support ongoing activity in HCFA and the DMERCs to develop more specific coverage guidelines and educate providers and suppliers about proper billing for such supplies. We hope the information contained in this report is helpful as they complete this activity.

OIG Studies of Other Nursing Home Supplies

The OIG will continue studies and audits related to its major initiative examining services and supplies provided to Medicare beneficiaries residing in nursing facilities. As this report and other OIG work has reflected, the fragmentation of billing for services and supplies provided to residents of nursing homes has created a host of improper incentives for billers to the Medicare program.

"Bundling" of Services

We continue to support HCFA's efforts to pursue a systematic solution to these kinds of problems through a requirement for "bundling" of services in nursing home settings. Under such an approach, the nursing home would be responsible for providing commonly needed services to residents of that facility, rather than allowing for separate billing by suppliers. Such a solution would eliminate the incentives suppliers now have to aggressively seek out patients in nursing homes and market their products inappropriately in those settings. It would also ensure that nursing homes take on appropriate responsibilities for services and supplies delivered to residents in their facilities.

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INTRODUCTION

PURPOSE

This report examines trends in allowances and questionable billing practices for incontinence supplies under Medicare Part B between 1990 and 1993.

BACKGROUND

Medicare Coverage of Incontinence Supplies

Incontinence is the inability of the body to control urinary and bowel functions. Reimbursement for incontinence supplies is included as part of Medicare's coverage for prosthetic devices. According to Medicare Carriers Manual section 2130, "prosthetic devices (other than dental) which replace all or part of an internal body organ (including contiguous tissue), or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ are covered when furnished on a physician's order."

Under the Medicare Part B program, the Health Care Financing Administration (HCFA) will reimburse suppliers that provide incontinence supplies to aid individuals whose incontinence condition "...is of long and indefinite duration." Certain items, such as absorbent undergarments or diapers, are specifically excluded from coverage.

Incontinence supplies include prosthetic devices such as catheters and external urinary collection devices such as pouches or cups. Catheters are flexible, tubular instruments used to control urinary flow. The HCFA will also reimburse accessories that aid in the effective and therapeutic use of these devices. These accessories include items such as drainage bags, irrigation syringes, sterile saline solutions, and lubricants. However, accessories are not covered in the absence of a prosthetic device.

Carrier Processing of Incontinence Supply Claims

In June 1992, HCFA issued a final rule designating four Durable Medical Equipment regional carriers (DMERCs) to process all claims for durable medical equipment, prosthetics, orthotics, and supplies. Effective October 1, 1993, the DMERCs replaced more than 50 area carriers which had previously processed DME claims. The geographical areas formerly serviced by the carriers were phased in under the DMERCs on a staggered basis. Each DMERC issued its own coverage and reimbursement policies that implement Medicare guidelines.

However, for urological supplies, the DMERCs issued a draft of a single national policy in October 1994. In addition to redefining and clarifying some of the definitions used in claims for incontinence and urological supplies, the policy establishes documentation requirements for higher than usual quantities of supplies. The non-

coverage of diapers and similar absorptive pads is emphasized. The policy also reinforces the condition of "permanence" for coverage purposes and stresses that accessories not used in conjunction with covered catheters or external urinary collection devices are not covered.

Medicare Fraud Alert

One DMERC issued a Medicare Fraud Alert in June 1994 describing a supplier scheme involving the marketing of incontinence kits to nursing homes. In this case, the supplier advised nursing home officials that Medicare was paying for the kits under a "pilot program." According to the alert, supplier representatives provide kits containing accessories such as syringes, saline solution, and lubricants, to the nursing home in exchange for beneficiary names and Medicare health insurance claim numbers. The marketing representative then orders bulk quantities of supplies billed under the beneficiaries' claim numbers.

The alert also indicated that the supplier marketing program stated that the beneficiary should be treated three times per day with the contents of the kit. This resulted in a supplier billing Medicare \$1,800 per month per beneficiary in one carrier jurisdiction.

METHODOLOGY

To determine the trends in incontinence allowances, we arrayed payment and utilization data for each incontinence supply. We also analyzed the utilization data for possible questionable billing practices.

We first reviewed each DMERC's coding and coverage guidelines and interviewed DMERC officials to identify 43 codes used to reimburse incontinence supplies. These did not include any "local" codes used by individual carriers. Supplies were segregated into three groups: catheters, external urinary collection devices, and accessories. The HCFA and DMERC officials provided the designation for each billing code.

We selected all services for 43 codes for a 1 percent sample of beneficiaries from the Part B Medicare Annual Data Procedure File for calendar year 1990 and the National Claims History 100% Physician/Supplier Data for calendar years 1991 through 1993. From the 1993 sample of 2,927 beneficiaries, we obtained an additional file for 231 beneficiaries who accounted for 51 percent of all incontinence allowances, beginning with the beneficiary with the highest amount billed. This file contained all Part B services, in addition to incontinence.

From the sample of incontinence services, we calculated Part B Medicare allowed payments, supply frequency, and number of beneficiaries. Allowed payments include both the 80 percent Medicare payment and the 20 percent coinsurance fee paid by beneficiaries. We arrayed the data by billing code, carrier, and major suppliers. We then analyzed the statistical information to determine trends in incontinence

expenditures. We limited our analysis for frequency utilization to the period 1991 through 1993 because frequency reported in 1990 was not comparable to later years.

According to DMERC coding policies, 11 of the 23 billing codes that cover accessories are also used to reimburse ostomy care. We did not include any services for the 11 codes associated with beneficiaries who received only ostomy care. We also did not include services billed under code A4323, "sterile saline irrigation solution," when it was not billed in conjunction with other incontinence supplies. According to DMERC officials, code A4323 may be used in conjunction with other non-incontinence supplies such as enteral nutrition products.

To determine the nature and extent of questionable billing practices, we interviewed DMERC officials including medical directors and fraud control unit personnel. We reviewed coverage and utilization standards for 1) the three Medicare carriers that were among the highest in allowances in 1993, 2) the current DMERCs, and 3) the proposed DMERC national urological standards.

We projected our findings by multiplying sample results by 100. Confidence intervals for our findings are presented in Appendix A.

We applied current and proposed DMERC guidelines to the services billed for the 43 incontinence supplies in 1993. We focused on two facets of billing: 1) accessories that can only be billed with prosthetic devices, such as catheters and external urinary collection devices; and 2) frequency limitations on prosthetic devices. For each practice, we reported Medicare allowances and frequencies above the tolerance guidelines by type of supply, carrier, supplier, and number of beneficiaries receiving supplies.

This report is one of a series of reports concerning Medicare payments for incontinence supplies. *Marketing of Incontinence Supplies (OEI-03-94-00770)*, describes supplier and nursing home practices that can lead to questionable payments and examines issues concerning Medicare beneficiaries' use of incontinence supplies. The third report, *Medicaid Payments for Incontinence Supplies (OEI-03-94-00771)*, will examine how the Medicaid program processes claims for incontinence supplies in 14 States.

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

FINDINGS

MEDICARE ALLOWANCES FOR INCONTINENCE SUPPLIES MORE THAN DOUBLED IN THREE YEARS DESPITE A DROP IN THE NUMBER OF BENEFICIARIES USING THESE SUPPLIES.

Medicare Part B allowances for incontinence supplies rose from \$88 million in 1990 to \$230 million in 1993, an increase of \$142 million. The most significant portion of that increase came in 1993 when allowances increased \$111 million, almost doubling from the previous year. Over the same time period, the number of beneficiaries receiving incontinence supplies has actually decreased. In 1990, 312,200 beneficiaries received incontinence supplies. In 1993, this figure fell to 292,700. Allowances per beneficiary more than doubled from \$282 in 1990 to \$786 in 1993.

Between 1991 and 1993, the number of incontinence supplies paid for by Medicare more than tripled. In 1991, Medicare Part B reimbursed suppliers for 19 million incontinence supplies. In 1992, reimbursed supplies increased to 25 million. In 1993, supplies more than doubled from the previous year to 60 million. The table below provides a summary of incontinence activity between 1990 and 1993.

Table 1. Incontinence Activity: 1990 - 1993

Activity	1990	1991	1992	1993
Allowances	\$88 million	\$108 million	\$119 million	\$230 million
No. of Beneficiaries	312,200	334,300	281,400	292,700
Allowances per Beneficiary	\$282	\$322	\$423	\$786
No. of Supplies	N/A	18.8 million	24.7 million	59.5 million

FOUR TYPES OF INCONTINENCE SUPPLIES ACCOUNT FOR ALMOST ALL THE INCREASE IN MEDICARE ALLOWANCES.

Between 1990 and 1993, Medicare allowances for irrigation syringes (billing code A4322), sterile saline irrigation solutions (A4323), lubricants (A4402), and female external urinary collection pouches (A4328) increased \$129 million. This accounts for 91 percent of the \$142 million increase for all supplies. The table on the next page shows increases in allowances for the four supplies according to their billing code.

Table 2. Increase in Four Supply Codes

Supply	1990 Allowance	1993 Allowance	Increase
Syringe	\$0.7 million	\$43.3 million	\$42.6 million
Saline Solution	\$7.0 million	\$47.0 million	\$40.0 million
Female Pouch	\$0.02 million	\$15.3 million	\$15.3 million
Lubricant	\$0.5 million	\$32.0 million	\$31.5 million
Total Increase			\$129.4 million

Although the total number of incontinence beneficiaries decreased 6 percent between 1990 and 1993, the number of beneficiaries receiving these four supplies showed significant increases. The table below displays the number of beneficiaries served for each of the four supply codes.

Table 3. Number of Beneficiaries Served for Four Supply Codes

Supply	1990	1993	Percentage Increase
Syringe	7,400	62,700	747 percent
Saline Solution	45,300	95,900	112 percent
Female Pouch	600	9,400	1,467 percent
Lubricant	5,700	59,900	951 percent

Allowances for accessories and collection devices rose significantly between 1990 and 1993 while allowances for catheters increased only modestly.

Allowances for accessories rose from \$61 million to \$183 million, an increase of 200 percent. In 1990, only \$198,900 was spent on all external urinary collection devices. By 1993, expenditures skyrocketed to \$16 million, an 8,051 percent increase. In contrast, allowances for catheters grew 15 percent from \$27 million to \$31 million between 1990 and 1993, an annual increase of 5 percent.

The nature of supply allowances has also changed. In 1990, indwelling catheters (A4338), bedside drainage bags (A4357), and irrigation trays (A4320) accounted for almost half of all allowances. By 1993, 53 percent of all allowances were made for irrigation syringes, sterile saline solution, and lubricants.

The rise in supply utilization mirrors the change in allowances. In 1991, Medicare paid for 19 million incontinent supplies. By 1993, this figure had tripled to 60 million. Suppliers were reimbursed for 63,200 external urinary collection devices in 1991 and

2 million in 1993, an increase of 3,410 percent. Female pouches account for almost 95 percent of the external urinary collection devices supplied in 1993. The number of catheters rose from 6 million in 1991 to 7 million in 1993. Intermittent urinary catheters increased 1.5 million but was offset by a decrease in the number of insertion trays, external catheters, and indwelling catheters.

Allowances are concentrated in one carrier and a small number of suppliers and beneficiaries.

One carrier and a small number of suppliers and beneficiaries account for a significant portion of allowances. Florida Blue Shield accounted for 55 percent of all incontinence allowances in 1993, while six carriers made 50 percent of the allowances in 1990. Of the 1 percent sample claims reviewed in 1993, less than 1 percent of all suppliers received total annual payments of \$50,000 or more, accounting for over one-quarter of all payments. In contrast, no supplier received total payments that exceeded \$50,000 in 1990. While 60 percent of the suppliers received total payments of \$100 or less in 1990, the number dropped to 40 percent in 1993. The following table details incontinence payments by supplier between 1990 and 1993.

Table 4. Incontinence Payments Per Supplier

Total Dollars Allowed	1990		1993	
	% of Suppliers	% of Allowances	% of Suppliers	% of Allowances
Under \$100	60.0	3.3	39.3	0.8
\$100-\$199	9.0	2.5	10.9	1.0
\$200-\$499	12.9	8.2	16.9	3.5
\$500-\$999	7.4	10.2	12.2	5.4
\$1,000-\$4,999	8.9	37.0	15.4	19.1
\$5,000-\$9,999	1.1	14.5	2.7	11.7
\$10,000-\$49,000	0.8	24.4	2.2	30.9
\$50,000+	0.0	0.0	0.5	27.5

In 1993, 10.3 percent of beneficiaries received services over \$2,000 and accounted for 57 percent of allowances. In 1990, payments were less concentrated in such large payments. Only 21 percent of allowances were made to beneficiaries who received \$2,000 or more in services. In 1990, 53 percent of beneficiaries received \$100 or less in incontinence supplies, while 33 percent received comparable payments in 1993. The table on the next page details allowances by beneficiary.

Table 5. Incontinence Allowances Per Beneficiary

Total Dollars Allowed	1990		1993	
	% of Beneficiaries	% of Allowances	% of Beneficiaries	% of Allowances
Under \$100	52.5	5.7	32.6	1.7
\$100-\$199	12.2	6.2	12.7	2.3
\$200-\$499	18.9	21.8	19.4	8.2
\$500-\$999	10.5	26.4	15.0	13.3
\$1,000-\$1,999	4.0	18.7	9.9	17.8
\$2,000-\$2,999	1.2	10.9	3.9	12.1
\$3,000-\$3,999	0.5	5.7	1.9	8.5
\$4,000+	0.2	4.6	4.5	36.0

QUESTIONABLE BILLING PRACTICES MAY ACCOUNT FOR ALMOST ONE-HALF OF ALL INCONTINENCE ALLOWANCES IN 1993

Medicare allowed \$107 million in 1993 for supplies related to questionable billing practices. This represents 47 percent of the \$230 million in allowances. About \$88 million was paid for incontinence accessories for beneficiaries who did not receive a prosthetic device. Additional payments of \$19 million were made for certain prosthetic devices that appear to have excessive utilization. These billing practices are concentrated in one carrier, few suppliers, and few beneficiaries.

Accessories billed without prosthetic devices do not meet Medicare guidelines.

In order for Medicare to pay for incontinence accessories the beneficiary must have a prosthetic device such as a catheter or a urinary collection device. However, \$88 million was allowed for accessories that were not billed with a prosthetic device. As shown in the table on the next page, virtually all allowances that did not meet Medicare guidelines were for just three supplies. The supplies were sterile saline solutions, irrigation syringes, and lubricants. In total, these three supplies account for 94 percent of the \$88 million in questionable billings. As a further check, we reviewed Part B services provided to 96 beneficiaries with large Medicare allowances and found that very few beneficiaries received other durable medical equipment for which these supplies would have been appropriate.

Table 6. Accessories Billed Without Catheter or Collection Device

Supply	No. of Supplies	Allowances
Saline Solution	6,467,500	\$29 million
Syringe	10,268,200	\$31 million
Lubricant	11,312,800	\$22 million
Subtotal for three supplies	28,048,500	\$82 million
All Supplies	29,290,400	\$88 million

Utilization for certain prosthetic devices appears excessive.

As much as \$19 million in allowances may have been overpaid if the proposed DMERC utilization standards had applied to certain prosthetic devices in 1993. Over \$11 million in 1993 was allowed for female external urinary collection pouches (A4328) that exceed the proposed DMERC guidelines of one per day. We are aware that at least one supplier was paid for 186 per month, or 6 per day. Another \$8 million was allowed for beneficiaries who received more than one indwelling catheter per month. The proposed DMERC policy calls for no more than one indwelling catheter per month for routine maintenance. Additional catheter changes are covered only if documentation substantiates medical necessity.

Florida Blue Shield accounted for most of the questionable allowances.

Florida Blue Shield accounted for \$78 million (89 percent) of \$88 million in Medicare allowances for accessories not billed in conjunction with a catheter or external urinary collection device. Over 90 percent of the allowances were for just three supplies: irrigation syringes, sterile saline solutions, and lubricants. Almost 70 percent of the allowances for female external urinary collection pouches was also through Florida Blue Shield.

The allowances for the indwelling catheters that exceeded one per month involved numerous carriers. Four carriers accounted for over 40 percent of allowances. The carriers were Pennsylvania Blue Shield (15 percent), Illinois Blue Shield (10 percent), Blue Shield of Greater New York (9 percent), and Nationwide of Ohio (7 percent). The remaining 60 percent was paid by 44 other carriers.

Allowances were concentrated in few suppliers.

Approximately 5 percent of suppliers (19 in the sample of 471) accounted for over three-quarters of the accessories billed without catheters or external urinary collection devices. All but one of these suppliers were paid by Florida Blue Shield.

Ten suppliers in our sample accounted for all payments for female external urinary collection pouches. All but three of the suppliers were paid by Florida Blue Shield. Only 3 of the 11 codes used to reimburse indwelling catheters showed any concentration of allowances for suppliers. For each of these codes, A4311, A4313, and A4315, one supplier received at least two-thirds of all allowances in our sample. The remaining allowances was shared by several suppliers.

Few beneficiaries receive most of the allowances.

A total of 821 beneficiaries (28 percent from the sample of 2,927) received accessories without a prosthetic device. At least 360 of these beneficiaries were billed for irrigation syringes, sterile saline solutions, and lubricants.

All the excessive allowances for female collection pouches were made to 3 percent of beneficiaries sampled. For each of the indwelling catheter codes except A4338, all excessive payments were made to 1 percent to 6 percent of the beneficiaries sampled. However, almost one-third of the beneficiaries in our sample received more than one catheter per month of those billed under A4338.

A PROPOSED CHANGE IN DMERC POLICIES WILL PROBABLY ADDRESS QUESTIONABLE BILLING PRACTICES.

Inconsistencies and the lack of clear utilization guidelines and controls among carriers contributed to the large number of questionable incontinence claims paid by Medicare in 1993. Current DMERC policies, while more consistent, still do not contain clear coverage definitions. A proposed draft DMERC policy further clarifies covered services and provides a mechanism to link incontinence accessory supplies to prosthetic devices.

Previous carrier policies did not contain clear guidance on coverage and appropriate utilization.

We reviewed policies of three carriers which were among the highest in incontinence allowances for 1993 and found that their guidelines differed for the same types of supplies. For example, for one indwelling catheter code, one carrier allowed two per month while another allowed eight. For one supply code, one carrier allowed 4 per day, the second allowed 1 per week, and the third allowed 30 per month. For the female urinary collection device (A4328), an item with a large number of questionable allowances, two carriers had no utilization guidelines and the third allowed four per month.

The carrier with the highest questionable allowances for 1993 had no frequency or utilization controls for any incontinence supplies except for two intermittent catheter codes. Neither this carrier nor the two other carriers had controls to prevent allowances for incontinence supplies when billed without a prosthetic device.

Current policies, while stronger, do not go far enough.

Current DMERC policies categorize the incontinence supplies benefit under coverage of prosthetic devices. For a prosthetic device to be covered, "the physician must certify that the condition resulting in the need for the device is of long and indefinite duration (at least 3 months)."

All four DMERCs have utilization controls for indwelling catheters, limiting the number of catheters to two per month for routine maintenance. Three DMERCs have strengthened coverage policies for lubricant, stating that it can no longer be reimbursed as a separate supply since it is included in catheter insertion trays.

The DMERCs have also adopted a uniform certificate of medical necessity form. This certificate must be filled out, signed, and dated by the ordering physician and kept on file by the supplier.

Not all DMERCs have computer edits or controls in place to ensure that supplier claims conform with DMERC policies. While all four DMERCs have a utilization standard for indwelling catheters, only two have computer edits. Only one DMERC has an on-line edit to check claims for particular supplies to ensure that the certificate of medical necessity adequately supports the use of these supplies.

Even though the DMERC manuals limit payment for supplies to those that are for the effective use of a prosthetic device, DMERCs do not have controls to prevent payment for incontinence supplies when the beneficiary has neither a catheter nor an external urinary collection device. Without these controls, Medicare will continue to pay for incontinence supplies that do not meet Medicare coverage guidelines.

The draft DMERC policy provides uniform coverage and utilization standards that will lead to improved processing of incontinence supply claims.

The proposed DMERC national guidelines on urological supplies will prevent Medicare payment for supplies not used with covered prosthetic devices. As the draft policy clearly states, "urological supplies that are not used with catheters or external urinary collection devices will be denied as noncovered." It provides even more explanation in the case of sterile saline solution and irrigation syringes by maintaining that "irrigation supplies that are used for care of the skin and/or perineum of incontinent patients are not covered."

The new policy requires suppliers to add a modifier to urological supply codes when the supplies are used with a catheter or external urinary collection device. The new ZX modifier, as it is known, would be added to the end of a code submitted on claims for catheters, external urinary collection devices, or supplies required for the effective use of one of these items. The modifier indicates that "specified coverage criteria in the medical policy have been met and documentation is available in the supplier's records."

If this policy is implemented and claims processing controls are created to ensure that required modifiers are used, large numbers of questionable allowances such as those found in 1993 can be avoided. If the policy had been implemented in 1993, Medicare and beneficiaries could have saved as much \$88 million in questionable payments.

The proposed policy provides more explicit definitions of covered items. It clearly defines female urinary collection devices, insertion trays, and anchoring devices. It also lists supplies sometimes paid for previously that will no longer be covered since they are not required for the effective use of incontinence prosthetic devices (e.g. skin barriers and appliance cleaners).

The policy also contains utilization standards for many incontinence supplies. For instance, no more than one indwelling catheter per month will be covered for routine catheter maintenance. The new policy allows only one male external catheter and one female pouch collection device per day. These new utilization standards coupled with computer edits or controls should significantly decrease the number of excessive incontinence supplies billed to Medicare.

NEXT STEPS

Incontinence Supplies

In response to the information presented in this report and a companion report, the Office of Inspector General (OIG) plans to:

- o initiate an audit review to examine in more detail payments made for incontinence supplies in order to determine if any overpayments are involved in this area; and
- o launch a national investigation in this area, examining potentially fraudulent practices by specific suppliers of incontinence supplies.

We also support ongoing activity in HCFA and the DMERCs to develop more specific coverage guidelines and educate providers and suppliers about proper billing for such supplies. We hope the information contained in this report is helpful as they complete this activity.

OIG Studies of Other Nursing Home Supplies

The OIG will continue studies and audits related to its major initiative examining services and supplies provided to Medicare beneficiaries residing in nursing facilities. As this report and other OIG work has reflected, the fragmentation of billing for services and supplies provided to residents of nursing homes has created a host of improper incentives for billers to the Medicare program.

"Bundling" of Services

We continue to support HCFA's efforts to pursue a systematic solution to these kinds of problems through a requirement for "bundling" of services in nursing home settings. Under such an approach, the nursing home would be responsible for providing commonly needed services to residents of that facility, rather than allowing for separate billing by suppliers. Such a solution would eliminate the incentives suppliers now have to aggressively seek out patients in nursing homes and market their products inappropriately in those settings. It would also ensure that nursing homes take on appropriate responsibilities for services and supplies delivered to residents in their facilities.

APPENDIX A

CONFIDENCE INTERVALS

We reported our findings by multiplying 100 by the point estimates in our samples. The point estimates represent the total allowance, number of supplies, or number of beneficiaries. The confidence intervals present the range of possible findings at the 95 percent level. The 95 percent confidence level represents approximately two standard deviations from the sample mean. The two standard deviations, or semi-width, is determined by multiplying 1.96 by the standard error of the sample mean. The variance from the point estimate is determined by multiplying the semi-width of by the sample size. The confidence interval is the plus or minus range of the variance from the point estimate.

The 95 percent confidence intervals are presented in the following tables.

Table 1. Incontinence Activity: 1990 - 1993 (p.4)

Year	Allowances		No. of Beneficiaries		Allowance Per Beneficiary	
	95% Confidence Interval	Projected Total	95% Confidence Interval	Projected Total	95% Confidence Interval	Projected Total
1990	+/- \$5,839,100	\$87,969,900	+/- 10,000	312,200	+/- \$19	\$282
1991	+/- \$7,544,939	\$107,504,300	+/- 10,000	334,300	+/- \$23	\$322
1992	+/- \$8,963,442	\$118,970,400	+/- 10,000	281,400	+/- \$32	\$423
1993	+/- \$15,579,562	\$229,949,200	+/- 10,000	292,700	+/- \$53	\$786

Table 2. Increase in Four Supplies Between 1990 and 1993 (p.5)

Supply	Year	95% Confidence Interval	Projected Total
Irrigation Syringe A4322	1990	+/- \$381,600	\$679,700
	1993	+/- \$3,308,200	\$43,271,800
Saline Solution A4323	1990	+/- \$1,365,700	\$7,035,500
	1993	+/- \$4,888,600	\$47,020,200
Female Pouch A4328	1990	+/- \$25,160	\$18,500
	1993	+/- \$2,643,800	\$15,295,200
Lubricant A4402	1990	+/- \$333,100	\$494,100
	1993	+/- \$2,766,300	\$31,958,300

APPENDIX A

CONFIDENCE INTERVALS

We reported our findings by multiplying 100 by the point estimates in our samples. The point estimates represent the total allowance, number of supplies, or number of beneficiaries. The confidence intervals present the range of possible findings at the 95 percent level. The 95 percent confidence level represents approximately two standard deviations from the sample mean. The two standard deviations, or semi-width, is determined by multiplying 1.96 by the standard error of the sample mean. The variance from the point estimate is determined by multiplying the semi-width of by the sample size. The confidence interval is the plus or minus range of the variance from the point estimate.

The 95 percent confidence intervals are presented in the following tables.

Table 1. Incontinence Activity: 1990 - 1993 (p.4)

Year	Allowances		No. of Beneficiaries		Allowance Per Beneficiary	
	95% Confidence Interval	Projected Total	95% Confidence Interval	Projected Total	95% Confidence Interval	Projected Total
1990	+/- \$5,839,100	\$87,969,900	+/- 10,000	312,200	+/- \$19	\$282
1991	+/- \$7,544,939	\$107,504,300	+/- 10,000	334,300	+/- \$23	\$322
1992	+/- \$8,963,442	\$118,970,400	+/- 10,000	281,400	+/- \$32	\$423
1993	+/- \$15,579,562	\$229,949,200	+/- 10,000	292,700	+/- \$53	\$786

Table 2. Increase in Four Supplies Between 1990 and 1993 (p.5)

Supply	Year	95% Confidence Interval	Projected Total
Irrigation Syringe A4322	1990	+/- \$381,600	\$679,700
	1993	+/- \$3,308,200	\$43,271,800
Saline Solution A4323	1990	+/- \$1,365,700	\$7,035,500
	1993	+/- \$4,888,600	\$47,020,200
Female Pouch A4328	1990	+/- \$25,160	\$18,500
	1993	+/- \$2,643,800	\$15,295,200
Lubricant A4402	1990	+/- \$333,100	\$494,100
	1993	+/- \$2,766,300	\$31,958,300

Table 3. Questionable Billing Practices (p.7)

Supply	95% Confidence Interval	Projected Total
Female Pouch	+/- \$3,070,135	\$11,117,300
Indwelling Catheter	+/- \$1,644,595	\$8,156,900
Sub-Total	+/- \$3,450,294	\$19,274,200
Accessories w/o Prosthetic Device	+/- \$10,784,752	\$87,570,500
Total	+/- \$10,574,064	\$106,844,800

Table 4. Saline Solution, Syringe, and Lubricant Billed Without Prosthetic Device (p.8)

Supply		95% Confidence Interval	Projected Total
Saline Solution A4323	No. of Supplies	+/- 1,296,309	6,467,500
	Allowance	+/- \$4,223,731	\$28,708,232
Irrigation Syringe A4322	No. of Supplies	+/- 1,238,503	10,268,200
	Allowance	+/- \$3,688,280	\$30,845,900
Lubricant A4402	No. of Supplies	+/- 1,562,456	11,312,800
	Allowance	+/- \$3,027,888	\$21,914,501

Table 5. Florida Blue Shield Allowance of Accessories Without Prosthetic Device (p.8)

Florida Blue Shield	95% Confidence Interval	Projected Total
	+/- \$9,890,931	\$77,949,800