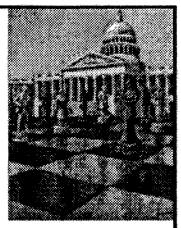
The 5th Annual National Congress on Health Care Compliance



All Roads Lead to the Pharmacy

Edwin D. Rauzi, ***Davis Wright Tremaine***
Grant Baumgartner, ***Arthur Andersen***

The 5th Annual National Congress on Health Care Compliance
February 8, 2002
Grand Hyatt Hotel
Washington, D.C.

The 5th Annual National Congress on Health Care Compliance

The Demographics You've Come to Know by Heart . . .

- Drugs as a percentage of health care spending (per HCFA/CMS)
  - 1995--5%
  - 1999--8%
  - 2010--14% (projected)
- New wonder drugs aren't the only thing that the Biotech revolution promises . . .

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Types of Pharmacies

- Retail
- Institutional
  - Hospital
  - Long-term care
  - Clinic
  - Hybrid/Mixed

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The Major Money Routes

- Interstates 1450 and 1500 *(Medicare)*
- State Roads One to Fiftysomething *(Medicaid)*
- ERISA and Medical Insurance Toll Roads *(Private Payers)*

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The Major Rules Routes

- State Roads One to Fiftysomething (special reserved lanes for other agencies, *e.g.*, Board of Pharmacy, Department of Health)
- The CMS Expressway
  - oncology drugs
  - inpatient
  - proposed expansion of benefits

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(more) Rules Routes

- The HIPAA Tunnel
- National Drug Numbers
- NCPDP -- The National Council for Prescription Drug Programs

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Major wrecks along the highway

- Walgreen's
- CVS
- Bayer
- Long's
- IPC/Pharmerica/Bergen Brunswig

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Walgreen's and CVS

- The prohibition against dispensing without a label
- "On-line adjudication
- The limitations of many computer programs
- = "Partial fills"

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Bayer's headache

- Average Wholesale Price
- Can wholesale be higher than retail?

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Long's

- The use of NDC numbers by Medicaid programs to determine payments
- The role of "post-its" in enforcement
- An old fact pattern with continuing significance

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IPC/Pharmerica/Bergen Brunswig

- The risks in industry "roll ups"
- Credits and returns

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Accidents Waiting to Happen

- Medicaid and pharmacy computers interacting
- Medicaid Rebate Program
- NDC numbers

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(more) Accidents Waiting to Happen

- Outpatient drugs
  - hospitals
  - long-term care
  - integrated delivery systems

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(more) Accidents Waiting to Happen

- CRNAs
- Single use/multi-use vials
- When is a generic not a generic?
- Metric Units
- "J" codes
- HCFA 1500 forms

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A few "fender benders" (so far)

- expired drugs
- usual and customary price
- CDM "shortcuts"

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Action along the "Big Pharma" Beltway

- Marketing
  - TAP Pharmaceuticals/Lupron
  - Caremark/Protropin
- Medicaid Rebates
- Average Wholesale Price (recall Bayer)

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The unique "engineering" challenges of the HIPAA tunnel

- Prescriptions as protected PHI
- Controversy over the use of NDC numbers
- Regulatory response to the "Sick Spouse" Syndrome

. . . and the answer is--
"Because that's where the money is."

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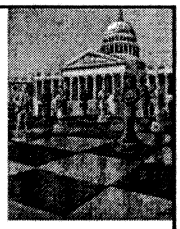

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Attachments

- NCDCP standards on billing units
- Excerpt from Bayer Corporate Integrity Agreement
- Excerpt from CVS Corporate Integrity Agreement
- Excerpt from Walgreen's Corporate Integrity Agreement
- Excerpt from Department of Justice 1998 Report
- Excerpt from Department of Justice 1999 Report
- Excerpt from Department of Justice 2000 Report

NCPDP STANDARD BILLING UNITS

THE STANDARD

The work group's goal was to devise a standard that:

1. Is simple and easy to use
2. Makes good business sense
3. Is already used by the majority of the industry
4. Provides for very few exceptions
5. Adds value for all who use pharmaceutical data

The principal rule of the standard is that there are only three billing units necessary to describe any and all drug products. These billing units are "each," "ml," and "gm." The use of "tablet," "capsule," "kit," and others is not appropriate, since these are dosage forms or package descriptions. Breaking billing units into dosage forms does not add value to the model and violates the goals of the standard. Whether an "each" refers to a tablet, a capsule, a suppository, or a transdermal patch, the price will be the same for each billing unit.

Since this definition is in place, the rest of the standard describes how the various types of pharmaceutical products fit into one of these standard billing units.

METRIC DECIMAL QUANTITIES AND THE STANDARD

Some general rules

The following general rules must apply and be issued as billing instructions to pharmacists. These instructions need not affect how a processor or state agency accumulates and reports quantities to HCFA for billing purposes. If the general rules are consistently followed, the state agency should be able to conduct data manipulations to accurately report dispensed quantities in the HCFA-required decimal metric units.

A. On broken packages, pharmacists must utilize the standard "apothecary conversions" in determining billed quantities (*i.e.*, one (1)-ounce liquid equals 30 ml, one (1)-ounce solid equals 30 gm) unless the package label of the manufacturer specifically states otherwise (*i.e.*, one (1)-ounce equals 28 gm).

B. When a package is dispensed whole (*i.e.*, in the original manufacturer's package site), pharmacists must bill the whole number metric quantity specified on the package by the manufacturer and "round up" any decimal metric quantities to the next higher whole number as further described below.

C. Until such time as metric quantities can be submitted and accepted any decimal metric quantities must be rounded up to the next whole number (*e.g.*, 3.5 gm should be rounded to 4.0 gm. Rounding up must occur before the calculation of total quantity that results from the dispensing of multiple packages. For example, if two (2) tubes of ophthalmic ointment in 3.5 gm packages are dispensed, the total quantity billed should be 8 gm not 7 gm.

Example:
Package Quantity Greater Than 1
Metaproterenol Sulfate Inhalation available in 2.5ml x 25 (unit price 0.5504 per ml). When dispensing 25 x 2.5ml, round the 2.5 to 3 and multiply by 25 = 75ml

Calculation of new unit price follows: 62.5 (metric decimal quantity)/75 (rounded quantity) x .5504 (unit price) = .458666 (adjusted unit price)

.458666 x 75 = 34.40 METRIC AMOUNT BILLED
.550400 x 62.5 = 34.40 METRIC DECIMAL AMOUNT BILLED
The package price remains constant, which is what is desired.

Package Quantity Less Than 1
Example is Lovenox available in 0.3ml x 10 (prefilled syringes)
Package price (0.3ml) = 16.80 Unit price (1 ml) = 56.00416

When dispensing the whole package, roundup from 0.3ml to 1ml x 10 (syringes) = 10ml

In this case, use the unit price:
10 (ml from rounding) x 16.80 (unit price) = 168.00 METRIC AMOUNT BILLED
0.3ml x 10 (syringes) x 56.00 (per ml) = 168.00
METRIC DECIMAL AMOUNT BILLED

D. Metric quantities must always be used in billing third-party programs.

E. The rounding up method is considered a short-term solution to the problem of decimal metric quantities, until such time as metric decimal quantities can be submitted and accepted (in field #442 of the optional claims information section). In the long term, pharmacists should be prepared to bill packages that specify a metric field in the telecommunication standard. Pharmacy computer systems should make use of field #442 as soon as possible by entering accurate metric decimal quantities dispensed. Processors may or may not be capable of using this field until the long-term solution is implemented.

AS ALWAYS, THE BILLED PRICE MUST BE ACCURATE ON A DECIMAL QUANTITY BASIS REGARDLESS OF THE QUANTITY SPECIFIED IN THE NON-DECIMAL UNITS FIELD.

The non-decimal metric quantity field must indicate quantities according to the rules above until that field is deleted from the standard and discontinued entirely or redefined to metric decimal quantity field.

Note: The apothecary conversions for broken packages will always apply.

PLACING PRODUCT CATEGORIES INTO THE STANDARD BILLING UNIT

Decimal metric quantities must be reported according to the short- and long-term "general rules" which appear earlier in this standard

1.0 Dosage form billed as "each"

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1.1. Solid oral dosage forms (tablets, capsules, etc.)

1.2. Injectable products, irrigation products, and/or inhalation products[1] – in powder-filled vials/amps/syringes, billed as a unit of "each" regardless of size or content of the vial in metric units.

1.3. Suppositories must be billed as the number of individual suppositories dispensed, *not the number of packages which may contain more than one suppository.*

1.4. Convenience packets, therapy packs, and/or oral contraceptives must be billed as the number of individual tablets or capsules (eaches) dispensed, *not the number of boxes or packages.*

1.5. Non-filled hypodermic syringes must be billed as the actual number of syringes and/or hypodermic needles dispensed (eaches). *Do not bill the number of boxes or plastipaks.*

1.6. Kits are defined as products with at least two (2) different or discrete items (excluding diluents, applicators, and activation devices) in the same package, intended for dispensing as a unit. Kits carry only a single National Drug Code (NDC). Kits are intended to be dispensed as a unit and should be billed as a unit of each kit dispensed.

1.7. Blood-derived products have varying potencies from batch to batch. Antihempohilic products must be billed as the number of antihemophilic units dispensed (each). Prolastin must similarly be billed as the number of milligrams dispensed (each).

1.8. Transdermal patches/powder packets must be billed as eaches, *not the number of boxes or packages.*

1.9. Unit of use packages with a quantity less than one becomes a quantity of "one each." This does not pertain to injectables. Examples of types of products included are: ointments in packets, eye drops in dropperettes.

2.0 Dosage form billed as "ml"

2.1. Liquid oral dosage forms (syrups/elixirs, etc.) must be billed as a unit of milliliter (ml).

2.2. Injectable products – liquid-filled vials/amps/syringes billed as the total number of milliliters (ml) dispensed.

2.3. Ophthalmics and otics – liquid ophthalmic and/or otic products must be billed as the number of milliliters (ml) contained in the package according to manufacturer labeling.

2.4. Reconstitutables – reconstitutable ophthalmic and/or otic products must be billed as the number of milliliters (ml) that are in the bottle at the time of dispensing, once the powder has been reconstituted with diluent, according to manufacturer's instructions.

2.5. Reconstitutable oral products must be billed as the number of milliliters (ml) in the bottle after reconstitution, according to the manufacturer's instructions.

[1] Multiple powder-filled vials or ampules with *only one diluent supplied* are still considered vials/eaches, not a kit.

3.0 Dosage form billed as "gm"

3.1. Ointments – must be billed as the number of grams (gm) in the package according to the manufacturer's labeling.

3.2. Bulk powder[2] billed as the number of grams (gm) dispensed.

4.0 Dosage form billed as "either ml or gm"

4.1. Inhalers and aerosols – all inhalers, inhaler refills, and aerosols should be represented as the metric quantity contained in the packaging in grams (gm) or milliliters (ml) as specified by the manufacturer on the labeling.

4.2. Topical products must be billed as the number of grams (gm) or milliliters (ml) in the container. *Do not bill the number of ounces dispensed or the number of packages dispensed.*

Dosage form billed as "exception"

Miscellaneous products – Several products do not fit into any of the above categories. These products should use the billing unit type specified below.

1. Cordran Tape (one each)
2. Test-Tape (one each)
3. EpiPen (one each)[3]
4. EpiPen Jr. (one each)[2]
5. Imitrex kit refill (one each)
6. Ventolin Rotacaps with Rotahaler (100 each, 24 each)[4]

[2] (footnote omitted).

[3] The question of the billing unit for the EpiPen products was a complicated one. Because EpiPen is a liquid in a disposable syringe, the billing unit standard assigned would normally be milliliters (ml). The complication occurs because even though the volume contained in the syringe is 2 ml, only 0.3 ml is delivered at the time the product is injected. There was a controversy over whether the package size should be 2 ml or 0.3 ml. Since there were good arguments for both sides, the consensus was that this product would be an exception and be called one "each" disposable syringe. There is no way to predict that other strange . . . situations may arise in the future, but the work group is committed to keeping such exceptions to a minimum.

[4] This is a temporary exception, pending FDA name change to Ventolin with Inhalation device.

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January 14, 2002

Edwin D. Rauzi
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Dear Mr. Rauzi:

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Additional information may be important to your participants. The information which you are providing is from the Billing Unit Standard Version 1.4. NCPDP WG2 Product Identification is working on an update to that Standard now.

NCPDP's Telecommunication Standard Version 5 and above do not support metric quantity. The standards require the use of metric decimal quantity. This alleviates the numerous problems that have arisen between business partners because of improper rounding. NCPDP continues to endorse exclusive use of the metric decimal quantity field in earlier Telecommunication Standard versions whenever possible.

Therefore, in the implementation of the HIPAA-named NCPDP transaction formats, the rounding of dispensed quantities *is no longer supported.* The membership approved the reporting of the dispensed quantities in the exact fractional amount including three decimal places. These transaction standards are the NCPDP Telecommunication Standard Version 5.1 and Batch Standard 1.0 (to be revised to Batch 1.1).

Excerpt from Bayer Corporate Integrity Agreement

Within one-hundred twenty (120) days of the Effective Date of the CIA, each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and will abide by Bayer Pharmaceutical Division's Code of Conduct. New Covered Persons shall receive and complete the required certification within two (2) weeks after becoming a Covered Person or within one-hundred twenty (120) days of the Effective Date of the CIA, whichever is later.

Bayer Pharmaceutical Division will annually review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Conduct shall be distributed within thirty (30) days of finalizing such changes. Covered Persons shall certify that they have received, read, understood and will abide by the revised Code of Conduct within thirty (30) days after distribution of such revisions.

2. ***Policies and Procedures.*** Within one-hundred twenty (120) days of the Effective Date of this CIA, Bayer Pharmaceutical Division shall implement written Policies and Procedures regarding the operation of its compliance program and its compliance with all of the Federal health care program requirements. At a minimum, the Policies and Procedures shall specifically address: 1) the subjects relating to the Code of Conduct identified in Section III.B.1; 2) the need to report accurate prices, including proper accrual determinations (based on reasonable assumptions that are regularly reviewed and for which appropriate adjustments are made, if necessary) for Government Reimbursed Products to the Health Care Financing Administration ("HCFA"), the State

Medicaid programs and all drug price reporting services on which government agencies rely; and 3) the requirements for marketing, selling and distributing Government Reimbursed Products in accordance with all applicable requirements of the Federal health care programs.

Within one-hundred twenty (120) days of the Effective Date of the CIA, the relevant portions of the Policies and Procedures shall be distributed to all Covered Persons. Bayer Pharmaceutical Division shall make available appropriate and knowledgeable staff to explain the Policies and Procedures.

At least annually (and more frequently if appropriate) Bayer Pharmaceutical Division shall assess and update as necessary the Policies and Procedures. Within thirty (30) days of the Effective Date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all Covered Persons whose job functions are related to those Policies and Procedures.

C. <u>Training and Education.</u>

1. ***General Training.*** Within one-hundred twenty (120) days of the Effective Date of this CIA, Bayer Pharmaceutical Division shall make its best efforts to provide at least three (3) hours of general training to each Covered Person. In the event that the Pharmaceutical Division is unable to complete the training within one hundred and twenty (120) days of the Effective Date of this CIA, it shall complete such training by no later than one hundred and fifty (150) days of the Effective Date. If any Covered Person has not completed the general training within this time period, a Covered Person

by the OIG made in writing as outlined in Section VI below and sent to the individuals named in Section VI below.

C. **Policies and Procedures.** To the extent not already accomplished, within one hundred twenty (120) days of the Effective Date of this CIA, CVS shall develop and initiate implementation of written policies and procedures. At a minimum, these policies and procedures should address CVS's corporate integrity program, CVS's compliance generally with applicable Federal health care program requirements, CVS's IAD, and CVS's Third Party Billing Department (hereinafter, collectively "Policies and Procedures").

In addition to other requirements as determined by the EBCC, the Policies and Procedures shall specifically address the manner in which CVS shall submit claims to the Federal health care programs for prescriptions that were only partially filled, i.e., where CVS is unable to fill the entire prescribed amount of medication to the program beneficiary or recipient due to inadequate inventory at such time (hereinafter, "partial-fill"). With regard to partial-fill situations, the Policies and Procedures shall continue to provide the following:

(1) the pharmacist will dispense a partial quantity (suggested 72-hour supply) of the prescription to the program beneficiary or recipient;

(2) at such time, no bill shall be submitted to the Federal health care program and no co-payment shall be collected from the program beneficiary or recipient;

(3) once the partial-fill has been completely filled in accordance with the prescription, and whether or not the program beneficiary or recipient has returned to pick up the prescription, CVS will bill the Federal health care programs and when the program beneficiary or recipient returns to collect the remainder of the prescription, CVS will collect the applicable co-payment from the program beneficiary or recipient in accordance with CVS's Policies and Procedures; and

(4) if the program beneficiary or recipient fails to return to collect the remainder of the prescription, the pharmacist shall cancel the prescription and return the unused medication to stock according to CVS's return to stock policy (hereinafter, "RTS Policy"). CVS then, in accordance with the CVS Reconciliation Process (as hereinafter defined), will reconcile with the applicable Federal health care program for any payment made to CVS by such Federal health care program for the undelivered prescription.

In addition, the Policies and Procedures shall continue to provide for the following with respect to the RTS Policy:

(1) upon cancellation of a medication for failure of the program beneficiary or recipient to return to collect the remainder of the prescription, the pharmacist notes on the prescription that the balance has not been filled and returns the unused medication to stock and reconciles the previous automated billing by deleting the prescription from its in-store claims processing system;

(2) the pharmacist must then reverse the transaction by overriding the price of the original partial-fill quantity to zero, input an override code to document the partial-fill, and reconcile with the applicable Federal health care program for any payment made to CVS by such Federal health care program;

(3) if the program beneficiary or recipient later returns and requests the balance of the prescription, the pharmacist must edit the prescription to the full quantity (by crossing out the "return to stock" or "RTS" note on the back of the prescription and indicating that the balance has been filled), the remainder of the prescription will be dispensed and the Federal health care program will be billed and the co-payment will be collected in accordance with CVS's Policies and Procedures;

(4) if a program beneficiary or recipient cancels a prescription for any reason after the prescription has been filled, but before the program beneficiary or recipient picks it up, the pharmacist must follow the preceding RTS procedure, including proper reconciliation with any applicable Federal health care program; and

(5) the pharmacist must perform, at a minimum, a RTS process every month; during this RTS process, any prescriptions that are not picked up by the program beneficiary or recipient after twenty eight (28) days from the dispense date, unless the program beneficiary or recipient specifically requests the pharmacist to hold the medication for a longer period of time, must be returned to stock in accordance with the RTS Policy, and the reconciliation process contained in the RTS Policy (hereinafter, the "CVS Reconciliation Process") must be followed.

If CVS has mailed any medication to a Federal health care program beneficiary that is returned to CVS and not ultimately delivered to the beneficiary, CVS shall follow the preceding RTS

procedure, including proper reconciliation with any applicable Federal health care program.

CVS shall only collect a single dispensing fee from the Federal health care programs for any partial-fill prescription. Also, in a partial-fill situation, CVS will not collect any additional co-payment amounts from program beneficiaries or recipients that exceed the total co-payment amount applicable to the prescription at issue.

In addition, the Policies and Procedures shall require CVS to accurately inform the program beneficiary or recipient of the amount of the prescribed medication that is available for dispensing. If a partial-fill is provided by CVS to a program beneficiary or recipient, CVS shall 1) provide accurate information to such person as to the reason for furnishing a partial-fill and 2) affirmatively inform such person that he or she was furnished with a partial-fill.

The Policies and Procedures shall also include methods for employees to make complaints and notifications about compliance issues to CVS's management through the Confidential Disclosure Program required in Section III.F below. CVS shall review and update the Policies and Procedures whenever appropriate. An index of the applicable Policies and Procedures will be provided to the OIG in the Implementation Report (as hereinafter defined in Section V.A). The Policies and Procedures will be made available by CVS to the OIG upon a request by the OIG made in writing as outlined in Section VI below and sent to the individuals named in Section VI below.

To the extent not already accomplished, within one hundred twenty (120) days of the Effective Date of this CIA, these Policies and Procedures shall be made available to all pharmacy/billing employees who provide services in CVS facilities or on CVS premises. In addition, pharmacy/billing employees who provide services in CVS facilities or on CVS premises shall receive training about these Policies and Procedures in accordance with the provisions of Section III.D below. Members of the EBCC, Store Managers, Team Leaders, Technician Trainers, Regional Healthcare Managers and District Managers, as appropriate, shall be available to explain any and all Policies and Procedures if necessary.

D. Training and Education Initiatives. CVS shall continue its training and educational initiatives. To the extent not already accomplished, within one hundred fifty (150) days of the Effective Date of this CIA, CVS shall provide appropriate training to each of its pharmacy/billing employees who provide services in CVS facilities or on CVS premises, which training shall in written or electronic summary form:

deems necessary. Revisions to the Code of Conduct shall be distributed and made available to pharmacy/billing employees within thirty (30) days of initiating such change.

C. Policies and Procedures. Except as otherwise noted below, within ninety (90) days of the effective date of this CIA, Walgreens shall develop and initiate implementation of reasonable written Policies and Procedures regarding compliance with this CIA and with all applicable Federal health care and State health care statutes, regulations, and guidelines, including the requirements of Medicare, Medicaid and other Federal health care programs.[1]

Included among the other issues that they address, the Policies and Procedures shall specifically address the manner in which Walgreens shall submit claims to Federal and state health care programs for prescriptions that are only partially filled *(i.e.*, where only a portion of the prescribed amount of medication is furnished on a given date to the customer who is a beneficiary of one of those programs). The Policies and Procedures shall provide that pharmacy/billing employees shall "reverse" claims submitted once it is determined that the pharmacy has insufficient inventory to immediately and fully fill any prescription. The Policies and Procedures shall ensure that, after such initial claim is reversed, a claim for a partially filled prescription may be submitted only for the quantity of medication available for immediate delivery. When Walgreens receives and prepares the remainder amount of the prescription for dispensing, it will "reverse" or adjust the claim submitted for the partial amount and submit a claim for the whole amount of the prescription.

[1] Walgreens is undertaking significant computer system changes in order to implement the partial fill policies specified herein. These changes have not been completed as of the effective date of this CIA. Walgreens commits itself to using its best efforts to diligently finalize and implement these computer system changes as soon as possible, but not later than one (1) year from the effective date of this CIA. Walgreens shall keep the OIG apprised of the status of its computer system changes and shall notify the OIG in the event of any significant delay in implementation of these computer system changes. Until the company-wide rollout of these computer system changes, Walgreens will continue to use its present policies for submitting claims in situations where prescriptions are partially filled. Walgreens shall commence to develop those Policies and Procedures specifically addressing the new partial fill computer procedures within ninety (90) days of the effective date of this CIA and shall it initiate implementation of those Policies and Procedures within ninety (90) days of the completion of the company-wide rollout of its computer system changes.

Walgreens shall ensure that it does not receive a second dispensing fee from any Federal or state health care program for dispensing the remainder of a partially filled prescription to a program beneficiary. The Policies and Procedures shall provide that Walgreens shall not collect any additional co-payment amounts from customers that exceed the total co-payment amount applicable to the prescription at issue.

The Policies and Procedures shall require Walgreens, if less than the full amount of prescribed medication is provided to a customer, to affirmatively inform the customer that he or she was furnished with less medication than prescribed and instruct the customer of the need to obtain an additional amount of the medication in order to comply with his or her physician's care instructions. The Policies and Procedures shall prohibit Walgreens from requiring any customer to make any statement, in writing or otherwise, which is false or misleading in order to receive the prescription which the customer is desiring to have Walgreens fill.

The Policies and Procedures shall include disciplinary guidelines and methods for employees to make complaints and notifications about compliance issues to Walgreens' Compliance Officer through a confidential disclosure program. Walgreens shall update the Policies and Procedures whenever appropriate. An index of the Policies and Procedures will be provided to the OIG in the Implementation Report. The Policies and Procedures will be available to the OIG upon request.

These Policies and Procedures shall be made available to all Walgreens' pharmacy/billing employees. In addition, the pharmacy/billing employees shall receive training related to these Policies and Procedures. Pharmacy Supervisors shall be available to explain any and all Policies and Procedures if necessary.

D. Training and Education. Within ninety (90) days of Walgreens' completion of its company-wide rollout of its computer system changes relating to partially filled prescriptions, Walgreens shall provide appropriate training to each of its

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Excerpts from
Health Care Fraud Report

Fiscal Year 1998

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EXECUTIVE SUMMARY

Since 1993, the Department of Justice (Department) has made fighting fraud and abuse in the health care industry one of the Department's top priorities. Health care fraud and abuse drains billions of dollars from Medicare and Medicaid, which provide essential health care services to millions of elderly, low income, and disabled Americans. The impact of health care fraud and abuse cannot be measured in terms of dollars alone. While health care fraud burdens our nation with enormous financial costs, it also threatens the quality of health care.

The Department has developed a balanced and responsible program to fight health care fraud and abuse. The first component of the Department's program focuses on enforcement efforts, including the use of criminal and civil tools. The second component emphasizes prevention and deterrence, through compliance initiatives for the health care industry and through public education to empower individual patients to be vigilant in identifying and reporting potential health care fraud schemes.

The Department's enforcement actions have proven results. In FY 1998, $480 million was awarded or negotiated as a result of criminal fines, civil settlements, and judgments in health care fraud matters. Under the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), $243 million was returned to the Medicare Trust Fund to support future beneficiary payments. Additionally, the Department reported that there were 326 defendants in 219 criminal cases that were convicted of health care fraud and abuse. At the same time the U.S. Department of Health and Human Services excluded more than 3000 individuals and businesses from participating in federal health programs, many due to criminal convictions.

The Department continues to prevent fraud and abuse in a number of ways: by encouraging providers to police their own activities through compliance programs; and by sponsoring consumer outreach initiatives, such as the consumer's fraud hotlines, to involve patients with first-hand knowledge in the detection of fraudulent practices. Settlement agreements with providers also emphasize future prevention efforts. Settlements in FY 1998 included 231 corporate integrity agreements, where providers agreed to change their operations so as to prevent fraud from recurring in the future.

The pace of legislative and industry change is altering the landscape of health care delivery and payment, presenting new challenges that must be planned for, both in prevention and enforcement efforts. The Department's continuing challenge in the future is to change the behavior of health care businesses so that they will take effective measures to prevent health care fraud schemes, while keeping enforcement efforts cognizant of the adverse impact of provider's conduct on the welfare of their patients.

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HEALTH CARE FRAUD: NATURE AND SCOPE OF THE PROBLEM

The Severity of the Problem

Health care fraud in the United States remains a serious problem that has an impact on all health care payers, and affects every person in this country. Health care fraud cheats taxpayers out of billions of dollars every year. Tax dollars alone do not show the full impact of health care fraud on the American people. Beneficiaries must pay the price for health care fraud in their copayments and contributions. Fraudulent billing practices may also disguise inadequate or improper treatment for patients, posing a threat to the health and safety of countless Americans, including many of the most vulnerable members of our society.

diabetes care, and another resident of Bishop Nursing Home died of the nursing home's failure to respond in an appropriate and timely manner to the resident's progressive weight loss and failed to treat his resultant pressure sores properly.

On August 19, 1998, in the District of Connecticut, the operator of Pioneer Valley Geriatrics (PVG) was sentenced to 21 month's incarceration, three years of supervised release, a $5,000 fine and $5,198 in restitution for defrauding Medicare. The operator pleaded guilty on April 3, 1998, to a one-count information charging him with mail fraud in connection with claims he caused to be submitted to Medicare in relation to services provided by PVG at Chesthelm Nursing Home in Connecticut, where PVG had contracted to provide mental health services to patients. The operator caused the presentation by PVG of claims to Medicare totaling $12,075 for 110 separate services of Chesthelm. These claims were represented as being performed by, or under the direct supervision of, a licensed medical doctor, but were not. Due to information that was discovered in an unrelated investigation months after the defendant was sentenced, the defendant filed a 2255 motion, seeking a resentencing related to whether he should have received an enhancement for obstruction of justice. The Government is consenting to the resentencing, at which time the court could impose the same sentence that was originally imposed.

On August 26, 1998, in the Eastern District of Michigan, an osteopath pleaded guilty to three counts of mail fraud and one count of accepting illegal kickbacks. The osteopath, who owned several Detroit area nursing homes, was charged with billing Medicare and Blue Cross/Blue Shield of Michigan for nursing home patient examinations that were either upcoded, or not performed at all. The osteopath was also charged with accepting more than $25,000 in kickbacks from a local hospice in return for recommending the hospice to the staff of the osteopath's nursing homes. As part of the plea agreement, the osteopath agreed to pay in full at the time of sentencing, $522,000 in restitution for the mail fraud violations and a $200,000 fine. He also agreed to pay restitution for losses resulting from the kickback scheme, which may exceed $700,000.

On August 13, 1998, in the Eastern District of Pennsylvania, a settlement was reached with the Department and HHS in which a Philadelphia nursing home will upgrade conditions to ensure that elderly and disabled residents are free from abuse and neglect and receive adequate treatment. The agreement, filed together with a lawsuit in the U.S. District Court in Philadelphia, stems from complaints about conditions at the Philadelphia Nursing Home (PNH) that were investigated by the Department. Under the agreement, the city of Philadelphia and Episcopal Long Term Care (ELTC), the city's contractor, will ensure that residents are free from mistreatment, abuse and neglect; provide adequate psychiatric, medical and nursing care, including daily activities that enable the residents to reach their highest practicable level of physical and mental well being; limit the use of restraints; work with a federal monitor to implement the agreed upon procedure; pay the Federal Government $50,000 to resolve FCA violations; and create a $15,000 fund for a special project, authorized by the United States, that will improve the quality of life for residents at PNH. A geriatric nurse practitioner appointed by the government at the nursing home's expense will visit the home at least monthly to monitor its compliance with terms of the agreement.

Pharmaceuticals and Pharmaceutical Services

On June 12, 1998, in the Eastern District of Pennsylvania, a Philadelphia pharmacist was

sentenced to four years in prison, and ordered to return the $700,000 he obtained through filing false claims for prescription drugs with insurance companies. The defendant, and his brother, operated four pharmacies between 1985 and 1995. The defendant was ordered to forfeit $700,000, and his brother was ordered to forfeit $1.4 million, and both were charged in a criminal information with a 10-year fraud on prescription drug plans involving sham prescription reimbursement claims supported by phony prescriptions; fictitious prescriptions supplied by street dealers in return for a share of the expected reimbursement; the use of drug samples obtained from doctors in return for cash or goods; and an illegal drug diversion of Schedule II controlled substances including Percocet, Vicodin, Xanax and Promethazine with Codeine. This case was charged and the defendants pled to RICO conspiracy.

On April 16, 1998, in the Southern District of Illinois, Home Pharmacy Services, Inc., a wholly owned subsidiary of Omnicare, Inc., entered into a Settlement Agreement to resolve its liability under the FCA. Home Pharmacy Services, Inc., was an institutional pharmacy that served nursing homes throughout southern Illinois. Almost all of the patients serviced were on Medicaid, paid by the Illinois Department of Public Aid (IDPA). The pharmacy would receive returned medicines from the nursing homes because a patient died or the prescription changed. The pharmacy would repackage and resell the returned pharmaceuticals and not credit IDPA for the returns. Home Pharmacy agreed to pay $5.3 million to settle the allegations of false claims. The former president of Home Pharmacy Services, Inc., pled guilty to felony false statements, and on September 21, 1998, was sentenced to 24 months imprisonment and ordered to pay $500,000 in restitution and a $250,000 fine. As part of the civil settlement, Home Pharmacy entered into a corporate integrity agreement.

On June 16, 1998, in the Southern District of Illinois, a Smithton resident pleaded guilty to making false statements to the Illinois Department of Public Aid concerning fraudulent bills submitted to that agency by Home Pharmacy Services (HPS), a Belleville, Illinois supplier of drugs and pharmaceutical products to nursing homes throughout southern Illinois. The defendant established a procedure in which medications which were returned to the pharmacy were placed back into inventory without crediting the Illinois Department of Public Aid which had paid for the drugs when first supplied to the nursing homes. The drugs were returned to HPS from the nursing home because the patients for whom they were prescribed had died. The drugs would be sent out a second time for other patients and Medicaid would be billed twice for the same medication. The defendant caused HPS to continue billing the agency even though he knew that HPS owed the agency in excess of $2 million. On April 10, 1998, HP's parent company, Ohio-based Omnicare, agreed to pay $5.3 million to settle *qui tam* allegations made by former employees of HPS.

Physicians and Other Practitioners

On December 9, 1997, in the Central District of California, an opthamologist agreed to pay the United States more than $375,000 to settle a *qui tam* suit brought by a former office manager. The suit alleged that the doctor routinely billed Medicare for endothelial microscopy for every cataract patient he treated, even though it is a rarely used pre-cataract surgical procedure, and despite the fact that the doctor never performed the procedure. The doctor agreed to implement a five-year compliance program in which he will have to pay for an annual audit of his practice and permit office searches by federal investigators at any time.

On August 19, 1998, in the District of Nebraska, a man who had represented himself to patients

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EXECUTIVE SUMMARY

The detection and elimination of health care fraud and abuse is a top priority of federal law enforcement. Our efforts to combat fraud were consolidated and strengthened considerably by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA established a national Health Care Fraud and Abuse Control Program (the Program), under the joint direction of the Attorney General and the Secretary of the Department of Health and Human Services (HHS)[1], acting through the Department's Inspector General (HHS/OIG), designed to coordinate federal, state and local law enforcement activities with respect to health care fraud and abuse. HIPAA brought much needed and powerful new criminal and civil enforcement tools and financial resources that permitted the government to expand and intensify the fight against health care fraud.

The third year of operation under the Program saw a continuation of the collaborative efforts of Federal and state enforcement and oversight agencies to identify and prosecute the most egregious instances of health care fraud, to prevent future fraud or abuse, and to protect program beneficiaries.

Civil and Criminal Enforcement Actions

Federal prosecutors filed 371 criminal indictments in health care fraud cases in 1999 -- a 16 percent increase over the previous year. A total of 396 defendants were convicted for health care fraud-related crimes in 1999. There were also 2,278 civil matters pending, and 91 civil cases filed in 1999.

Monetary Results

In 1999, the federal government won or negotiated more than $524 million in judgments, settlements, and administrative impositions in health care fraud cases and proceedings. As a result of these activities, as well as prior year judgments, settlements, and administrative impositions, the federal government in 1999 collected $490 million. It should be noted that some of the judgments, settlements, and administrative impositions in 1999 will result in collections in future years, just as some of the collections in 1999 are attributable to actions from prior years.

Nearly $369 million of the funds collected and disbursed in 1999 were returned to the Medicare Trust Fund. An additional $4.7 million was recovered as the federal share of Medicaid restitution.

Exclusion from Federally Sponsored Programs

HIPAA expanded and strengthened the government's ability to prohibit companies or individuals who have been convicted of certain health care offenses, lost their licenses, or engaged in other professional misconduct from participating in Medicare, Medicaid or other federally sponsored health care programs. In 1999, HHS excluded 2,976 individuals and entities.

Collaboration

One of the fundamental principals of the Program is to maximize the effectiveness and efficiency of law enforcement efforts by promoting information sharing and collaboration among the many federal, state and local allies in the fight against health care fraud. Such collaboration has increased during 1999, through heightened data sharing, establishment of a National Health Care Fraud Task Force chaired by the Deputy Attorney General (bringing together federal, state, and local prosecutors and other enforcement officials) and joint training, to name a few. In addition to the many joint health care investigations undertaken daily across the country, collaborative efforts have also produced effective new beneficiary outreach initiatives, and fraud prevention efforts.

Preventing Health Care Fraud

Preventing health care fraud and abuse is a central component of the Program. The Program's prevention efforts include the promulgation of formal advisory opinions to industry on proposed business practices, industry-specific program compliance guidance, special fraud alerts, corporate integrity agreements with providers who settle allegations of fraud, and beneficiary and provider education and outreach. Fraud prevention and compliance efforts are reaping significant results; the most recent audit of the Medicare payment error rates showed a $10.6 billion or 45 percent drop in improper fee-for-service payments over the last two years.

Administrative Penalties for "Patient Dumping"

The government expanded its efforts under the Patient Anti-Dumping Statute, which requires hospitals' emergency departments to provide emergency medical screening and stabilizing treatment, entering settlement agreements with 60 hospitals and physicians, and received one default judgment for a total of 61 individuals and entities -- up from a previous high of 53 settlements in 1998. The Government collected $1.725 million in civil monetary penalties associated with these cases.

INTRODUCTION

The reports recommended that HCFA instruct Medicare fiscal intermediaries to provide more training to facility and therapy staff on Medicare coverage criteria and guidelines, local medical review policies, and monitoring procedures for therapy and adequately fund Medicare contractors to perform medical reviews of therapy.

Focus on Collaboration

Federal-State Audit Partnership. In 1994, the HHS/OIG initiated a partnership between federal and state auditors to enhance and provide broader audit coverage of the Medicaid program. Collaboration among HHS/OIG, State auditors, inspectors general, Medicaid agencies and HCFA maximizes scarce resources at both the Federal and State levels. The focus of the partnership effort is not on the traditional identification and recovery of unallowable Medicaid costs; rather the program focuses on identifying program improvements and reducing the cost of providing necessary services to Medicaid recipients. HHS/OIG auditors provide computer support, audit programs and guides, training, information-sharing and other specialized assistance to State auditors, as well as direct audit support.

To date, active partnerships flourish in 22 states. This partnership effort has been a resounding success. State auditors have shown a great interest in creating partnerships and we continue to get inquiries on other potential joint projects. By the end of 1999, these State partnerships generated approximately $145 million in Federal and State savings since the partnership began. Many of these recommendations related to Medicaid prescription drugs.

Roundtable on Compliance. In conjunction with the health care industry, the HHS/OIG conducted a joint roundtable on health care compliance to gain new insights into the challenges of creating effective compliance programs. The event reflects HHS/OIG's commitment to engage in ongoing discussions with the health care compliance industry about practices and policies related to compliance programs, including the impact of compliance recommendations advanced by HHS/OIG. More than 125 compliance officers, government representatives and others attended the event.

Self-Disclosure Protocol. In October 1998, the HHS/OIG implemented a self-disclosure program, to assist providers and suppliers in investigating and reporting potential violations of Federal health care laws. The program offers providers an opportunity to police themselves, correct underlying problems and work cooperatively to resolve these matters. Since issuance of the protocol, 40 health care providers have submitted self-disclosures to the HHS/OIG. Two of these were successfully resolved through the return of overpayments to the Federal Government; the others are under investigation.

Data Sharing. With the increased focus on investigations that are national in scope, close collaboration among investigative and prosecutive agencies has become critical. To this end, the HHS/OIG Office of Investigations and the FBI have initiated an efficient information sharing system. Copies of all healthcare fraud referrals and allegations received by HHS/OIG are sent to the FBI Health Care Fraud Unit at FBI Headquarters. The FBI then serves as an informational contact and dissemination point for DOJ and its prosecutors nationwide. In turn, the FBI provides information on their health care investigative matters to HHS/OIG. All such cases, wherever generated, are entered into the HHS/OIG Case Information Management

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Monetary Results

In 2000, the federal government won or negotiated more than $1.2 billion in judgments, settlements, and administrative impositions in health care fraud cases and proceedings. As a result of these activities, as well as prior year judgments, settlements, and administrative impositions, the federal government in 2000 collected $717 million. More than $577 million of the funds collected and disbursed in 2000 were returned to the Medicare Trust Fund. An additional $27 million was recovered as the federal share of Medicaid restitution.

Enforcement Actions

Federal prosecutors filed 457 criminal indictments in health care fraud cases in 2000 -- a 23 percent increase over the previous year. A total of 467 defendants were convicted for health care fraud-related crimes in 2000. There were also 1,995 civil matters pending, and 233 civil cases filed in 2000. In 2000, HHS excluded 3,350 individuals and entities from participating in the Medicare and Medicaid programs, or other federally sponsored health care programs.

and ways to address quality of care given the unique situations in the various states. In June 2000, a national meeting of representatives of state working groups' was held to address the challenges and successes of training programs for prosecutors, investigators and other law enforcement officials, with an emphasis on the development of "best practices" and the use of inter-agency efforts to combat health care fraud.

Data Tech Conference. The National Health Care Fraud Task Force called for an examination of the use of information technology in detecting health care fraud and abuse. In June of 2000, HCFA and DOJ fulfilled this goal by co-sponsoring a national conference, which explored technologies and approaches to combat health care fraud and abuse in the 21st Century. The conference drew nearly 300 attendees from a wide universe of health care program and law enforcement officials dedicated to combating fraud and abuse in Medicare, Medicaid, and other government health programs. Attendees included staff from HCFA Central and Regional Offices, Medicare contractors, TRICARE, Medicaid State Agencies, other Federal health programs, State Medicaid Fraud Control Units, U.S. Attorney's Offices, the FBI, the DCIS, the HHS/OIG and other federal and state law enforcement agencies.

The conference focused on two basic themes. The first was an exploration of where technology is driving the science of fraud detection in the 21st Century. Tools incorporating advanced data mining, neural networking, fuzzy logic and artificial intelligence hold great promise for identifying program vulnerabilities earlier than ever. The second theme addressed approaches to combating fraud and abuse. Advancing technology makes it all the more vital that all stakeholders involved in combating health care fraud and abuse maintain close partnerships. Because bad actors do not discriminate among health programs they defraud, joint program integrity efforts are increasingly important.

- **Stepped up exclusion efforts.** Federal, state and local prosecutions are critical to protecting the integrity of our programs by prosecuting dishonest providers. State Licensing Boards play a vital role in protecting quality of care providing to our beneficiaries," said June Gibbs Brown, HHS Inspector General. "Exclusion from these programs is a second equally powerful tool in our fight against waste, fraud and abuse. We will be expanding our efforts to educate prosecutors and state licensing authorities about this critical tool, and the increase number of referrals. In part because of these efforts, exclusions in 2000 were at a record high — a total of 3,350 individuals and entities were excluded from participation in Federal programs. This is a 12.56 percent increase from 2,976 exclusions in 1999.

Other significant collaborative efforts during 2000 included:

Drug Pricing. Efforts continue to ensure that the government pays providers only reasonable and appropriate amounts for prescription drugs. Toward this end, allegations of false claims were settled in principle with a major drug manufacturer for inflating reported drug prices. These reported prices are relied on by the federal and state governments to set reimbursement rates for Medicaid; accordingly, the overstated reports allegedly caused providers to submit inflated reimbursement claims to Medicaid. Allegations were also settled that the drug manufacturer knowingly underpaid Medicaid for rebates owed to it under the Medicaid Rebate Program. The company agreed to pay $14 million, and agreed to a 5-year corporate integrity agreement under which it will change its drug pricing practices, and submit to monitoring. The agreement will be finalized when it has been ratified by participating states.

The HHS Office of Inspector General continued evaluations focused on HCFA methodologies for setting Medicare prescription drug prices. Although Medicare Part B does not cover most prescription drugs, it does reimburse for those used in conjunction with certain durable medical equipment and some that are furnished during dialysis. HHS/OIG studies concluded that the Medicare program could save dramatic sums of money if it reimbursed for the drug albuterol and certain end stage renal disease drugs at the same rate as Medicaid, and achieve even more savings if it could use rates available to the Veterans Administration (VA). For example, savings for albuterol would reach $120 million if Medicaid rates were available to the Medicare program; and $209 million at the VA acquisition rates. Medicare allowed amounts would be nearly halved for five ESRD drugs if amounts were based on the rates available to the VA.

HCFA's methodology for reimbursing for drugs is set by statute -- very generally, Medicare reimburses for the Average Wholesale Price (AWP) of drugs, less 5 percent. HCFA has sought legislative change under which Medicare reimbursement would more closely approximate actual acquisition costs; however, these proposals have not been passed by the Congress. Partly in response to recent enforcement efforts, in September, HCFA alerted its contractors through a Program Memorandum that new, more accurate estimates of AWP for 32 drugs were available, and could result in potential savings of $400 million per year. Contractors may take advantage of the new pricing data beginning in 2001. Section 429(c) of P.L. 106-554, establishes a moratorium on decreases in payment rates for drugs and biologicals furnished on or after January 1, 2001, until review of a Comptroller General study on appropriate payment methodologies.

Healthcare Integrity and Protection Data Bank. HIPAA mandates that the OIG and Department of Justice establish a national health care fraud and abuse data collection program, for the reporting and disclosure of certain health care related final adverse actions taken against health care providers, suppliers and practitioners. The data collection program, named the Healthcare Integrity Protection Data Bank (HIPDB), has been developed as an electronic system that will collect, store and disseminate reports on civil, criminal and administrative actions submitted by Federal and State agencies and health plans. These Federal agencies and entities are also eligible to query the HIPDB. Although the OIG retains policy oversight authority over the HIPDB, the OIG has arranged with Health Resources and Services Administration (HRSA), through an Memorandum of Understanding, to run the day-to-day operations of the HIPDB. The HIPDB became operational on March 6, 2000. Since becoming operational, the HIPDB has averaged between 20,000 and 25,000 queries per week.

A more detailed description of these and other accomplishments of the major federal participants in the coordinated effort established under HIPAA follows. While information in this report is presented in the context of a single agency, most of these accomplishments reflect the combined efforts of HHS, DOJ and other partners in the anti-fraud efforts. The continuing accomplishments of the DOJ and HHS and our partners in the coordinated anti-fraud effort, as well as prevention efforts, demonstrate that the increased funds to battle health care fraud and abuse continue to be sound investments, as well as good public policy.
