SIDLEY AUSTIN LLP

SIDLEY

BEIJING BRUSSELS CHICAGO DALLAS FRANKFURT GENEVA HONG KONG LONDON LOS ANGELES NEW YORK SAN FRANCISCO SHANGHAI SINGAPORE SYDNEY TOKYO WASHINGTON, D.C.

The 2009 OIG Work Plan: The Agency's Priorities

William A. Sarraille
Eileen L. Kahaner
Hae-Won Min Liao
October 23, 2008

Overview

- Insights from the Work Plan
- Special Focus on Pharmaceutical
- Special Focus on Device Manufacturers
- Special Focus on Clinical Trial Research Issues
- Medicare Part C (Medicare Advantage)
- Hospitals
- Home Health Agencies
- Nursing Homes
- Hospice Care
- Physicians and Other Health Professionals
- Durable Medical Equipment and Supplies
- ESRD-Related Initiatives
- Medicare Part A and Part B Contractor Operations
- Medicaid Issues

Insights from the Work Plan

- Provides valuable information regarding OIG's focus for the upcoming year
  - Especially important as we enter a health reform cycle
- Highlights vulnerabilities in federal health care programs
- A mixed collection of "policy" and "enforcement" related issues
  - Office of Audit Services (OAS) performs majority of projects identified in Work Plan
  - Office of Evaluation and Inspections (OEI), however, undertakes a significant number of reviews
- Contains both "work in progress" and "new starts"
- Providers and manufacturers are not the only targets of reviews
  - Others include the States, contractors, and HHS agencies (including CMS and FDA)
  - The indirect effect of these reviews on providers and manufacturers

Special Focus on Pharmaceutical Manufacturers

- Increasingly important component of OIG Work Plans
  - Although drug and device issues continue to be "mixed in" other discussions, separate discussions are now present as well
- The OIG's institutional interest in addressing this important enforcement priority

Part B Payments for Prescription Drugs

- Payments to dialysis facilities for Epogen administration
  - Reflects continuing importance of Epogen in drug policy debate
  - Revealing its focus, OIG notes services must be "completely and accurately documented"
    - Suggestion that an exacting standard will be applied.
  - Contractor oversight also to be reviewed
- Oversight of manufacturers' ASP submissions (work in progress)
  - Timeliness and accuracy
- Both manufacturers' and CMS' oversight to be reviewed Compare Average Sales Prices (ASPs) to both Widely Available Market Prices (WAMPs) and Average Manufacturer Prices (AMPs) (new start)
  - Could set the stage for the assertion of alternative reimbursements under the new Presidential administration

Other Part B Drug Issues

- Medicare payment for chemotherapy drug administration (work in progress)
  - MedPAC noted 217% increase in administration payments from 2003 to 2004, while drug payments only increased 4%
  - Relationship of MedPAC and OIG work
  - May have influenced pending proposed reimbursement rules

Clotting Factor Furnishing Fees

- Based on GAO recommendation, MMA (Section 303) created a clotting factor furnishing fee to cover the costs of providing the factor to Medicare beneficiaries
- Review will determine "whether providers performed all of the services covered by the furnishing fee"
- A "new start" for 2009

Part B Payments for Prescription Drugs (cont'd)

- Medicare home health outlier payments and insulin injections
  - Normally insulin is not covered by Part B, but, where a patient is physically or mentally impaired and is unable to inject, home health coverage may apply
  - Part of wider focus on potentially improper outlier payments
- Review aberrant claim patterns for inhalation drugs in South Florida to identify potentially fraudulent billing practices
  - 19% of $900 million 2006 Medicare spending in this area
  - Clear fraud focus to review

Medicare Part D Issues (cont'd)

- OIG, echoing prior statements, says "oversight of Medicare Part D [is] in our of list of HHS' management challenges"
- Identification of Fraud and Abuse as a major point of emphasis
  - OIG lists several programs explicitly related to the identification and detection of fraud and abuse under the Part D program
    - Review the extent to which Part D sponsors identify potential fraud and abuse
      - Will examine if sponsors make inquiries, initiate corrective actions, and make referrals regarding potential fraud and abuse (work in progress)
    - Assess the volume of Medicare Prescription Drug Integrity Contractors (MEDIC) reporting of fraud and abuse and their referrals to law enforcement (work in progress)
      - Also their "contractual adherence" (new start)

Medicare Part D Issues

- Reconciliation Calculations
  - OIG will also review various aspects of the Medicare Part D reconciliation calculations
    - Three different reviews (one new start; two works in progress)
  - In a component of the work that may have manufacturer implications, the audits will include review of "discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, upfront discounts, coupons, goods in kind, free or reduced-price services, grants, or other price concessions."
- Related review of plan bid submissions (work in progress)
  - OIG pointedly observes that "CMS Bid Instructions require sponsors to report all rebates . . . . Specifically, all rebates and price concessions not used to directly reduce the cost at the point of sale must be included . . . . Further, rebates and price concessions must be reported in full."
- Retiree Drug Subsidy Program (work in progress)
  - Review the eligibility issues related to a sample of payments made to plan sponsors and the supporting costs
  - Again, in a component that may implicate manufacturers, the OIG notes that "costs actually paid" must be "net of any discounts, rebates, or other price concessions."

Medicare Part D Issues (cont'd)

- Duplicate Payment Concerns
  - Various plans to review the potential for duplicate payments for Medicare D prescription drugs
    - Hospice, Part A, Part B, and SNF are the focus of new starts or work in progress
  - Review of CMS' coordination and oversight to ensure it is sufficient to prevent duplicate payments for prescription drugs as its own item
  - Could be relevant to the B/D coordination debate.

Other Part D Issues

- Analysis of the accuracy of Part D sponsors' tracking of beneficiaries' true out-of-pocket costs (new start)
  - Could involve review of patient assistance issues
- Aberrant Part D claims (work in progress)
  - "[D]eviat[ions] from the usual patterns of claims"
  - Claims for Schedule II drugs the only example listed
- Review of the prices listed in the Medicare Prescription Drug Plan Finder (work in progress)
  - Verification of the use of low cost-sharing amounts for patients in Part D catastrophic coverage (new start)

Additional Part D Issues

- Comparison of pharmacy reimbursement amounts in Part D and Medicaid (work in progress)
  - Related to Congressman Waxman's concerns about the relationship between Medicaid and Part D rebates
  - Undisclosed "sample of drugs to be used
- Medication Therapy Management Program (work in progress)
  - Review whether Part D sponsors have enrolled qualified beneficiaries into a medication therapy management program (MTMP) and whether the MTMPs have conformed to Federal regulations
- E-Prescribing
  - Examine the extent to which Part D sponsors have adopted CMS' standards for e-prescribing
- Pass-Through (work in progress)
  - Analyze the implementation of provisions associated with the pass-through of negotiated drug prices to the Medicare program and of CMS' oversight of the pass-through of negotiated price concessions

Additional Part D Issues

- Still More Part D Initiatives
  - Review CMS' and Part D sponsors' oversight of PBMs to determine, in part, whether the contracts between these parties include provisions required by federal regulations (new start)
  - Analyze the impact of drug rebates, if any, on the drug utilization of long-term care pharmacies (new start)
    - Reflection of the fact that "CMS [has] raised concerns" about LTC pharmacy practices
    - Issues include clinical appropriateness of drugs supported by incentives and the "utilization" of those drugs
      - Appears potentially to include swapping issues
  - Verify whether Part D sponsors reporting mid-year formulary changes to CMS are complying with regulatory requirements

Medicaid Prescription Drugs

- Accuracy of Price Reports Submitted by Manufacturers
  - Calculation of AMPs, BPs, and URAs under the AMP Final Rule (new start)
    - "Selected" manufacturers to be reviewed
    - Selection criteria not disclosed
    - To be completed in FY2010
  - Review whether manufacturers timely report AMPs to CMS during CY 2008 (new start)
    - Accuracy a concern, too
    - Link to 340B pricing an area of concern
  - Analyze the accuracy of manufacturer submissions of AMPs for FUL "outliers" (work in progress)
    - Seeking to see if these outliers were "reported correctly"

Medicaid Prescription Drugs (cont'd)

- Review accuracy of drug type classification within the Medicaid Drug Rebate Program (work in progress)
- Determine whether the inflation penalty component of the Medicaid drug rebate law was correct (new start)
  - Will involve a review of base date AMP issues

Medicaid Prescription Drugs (cont'd)

- States' Efforts Related to Medicaid Claims
  - Review whether the States' submission of Medicaid drug claims to CMS for reimbursements are correct and supported for the drugs claimed (work in progress)
  - Assess whether a State's Medicaid claims for compounded drugs and drug components complied with Federal requirements for reimbursement and the collection of Medicaid rebates (work in progress)
  - Conduct follow-up reviews of physician-administered drug rebate collection (work in progress)

Medicaid Prescription Drugs (cont'd)

- Comparison of Medicaid FULs to Wholesale, Retail, and Medicare Pricing (work in progress)
  - Review how FULs calculated with pre-DRA methodology compare to the following pricing points
    a. the estimated pharmacy acquisition costs of drugs available through wholesale distributors
    b. retail prices available through discount programs at large chain pharmacies
    c. the average Part D pharmacy reimbursement account for all FUL drugs in the fourth quarter of 2007

Focus on Off-Label Uses

- A significant and important point of emphasis
- Medicaid reimbursement for unapproved drugs (work in progress)
  - Where not FDA approved or supported by official drug compendia
    - "Preliminary analysis of Medicaid payment data indicates that the program may be paying for drugs that have not received FDA approval."
- An additional review will look at Medicaid payment for unapproved pediatric drugs

Focus on Off-Label Uses (cont'd)

- Review of nursing home residents aged 65 or older receiving "selected" antipsychotic drugs "in the absence of conditions approved by . . . FDA"
  - Cites right of SNF patients to be free of "chemical restraints administered for discipline and convenience"
  - Criteria by which SNFs will be "selected" not identified
    - But references Part B and Part D coverage
- Review of renal dialysis facilities' compliance with FDA dosing guidelines for erythropoiesis stimulating agents (ESAs) (new start)
  - Function of FDA issuance of "black box" warning in 2007

Device Related Reviews

- Medicare Colonoscopy Services (new start)
  - Issues "properly supported, billed, and paid in accordance with Medicare requirements"
    - Biopsies and removal of polyps, tumors, and other lesions
    - Related consultations and office visits
      - Whether separately billable
- Medicare billings with "GY" modifier (new start)
  - Used to secure Medicare denial for statutorily excluded or otherwise non-covered services
  - OIG notes 53 million claims for $400 million in FY2006
  - Important issue for some Medical devices, such as non-covered ocular implants
  - OIG sees an important beneficiary protection issue

Other Device Related Issues

- Review appropriateness of the methodology for setting ASC payment rates under the revised ASC payment system (new start)
  - Section 626(b) of the MMA
- FDA oversight review of post-marketing studies of medical devices (new start)
  - Refers to 2006 OIG study of drugs which "found that FDA could not readily identify whether or how timely such post-marketing study commitments were progressing."
  - Consistent with the increasing focus in Congress and elsewhere on drug and device safety
  - "Level of compliance" by sponsors will specifically be reviewed
- Adverse effect reporting for medical devices (work in progress)
  - FDA oversight focus

Special Focus: Clinical Trial Research Issues

- Multiple reviews of CDC, FDA, and other agencies regarding "select agent" regulation compliance and transfer restrictions
  - No surprise in light of government's conclusions in the anthrax case
- Review of use of foreign clinical trials in support of FDA submissions (work in progress)
  - Qualifications of investigators and research sites
  - Compliance with "ethical principles" requirements
  - Relates to 2007 OIG finding that "FDA is often unaware that foreign trials have been conducted until after the results are submitted" to FDA

Medicare Part C (Medicare Advantage)

- Analysis of administrative costs included in Medicare Advantage bid submissions (new start)
  - In a noteworthy understatement, OIG states that "Congress has expressed interest in how MA plans determine . . . administrative costs."
  - OIG also states that previous reviews "found insufficient documentation of administrative costs and improper allocation of administrative costs."
- Investment income earned by MA plans (work in progress)
  - Aims to ensure that this income is used "to benefit Medicare enrollees."
- Review the appropriateness of Medicare reimbursements paid to critical access hospitals for services provided to MA beneficiaries (new start)

Medicare Part C (cont'd)

- Review of disenrollment of MA beneficiaries (work in progress)
  - Cost of providing medical services to disenrollees "800 percent [higher] in the first 6 months after disenrollment."
  - Appears to be assessing whether improper disenrollments have occurred.
- Examination of beneficiary appeals in the MA program (work in progress)

Initial Questions?

Hospitals

- Coding
  - Assessment of the new Medicare Severity Diagnosis Related Group (MS-DRG) system and coding trends under the new system
  - Review of the appropriateness of Medicare payments for x-rays performed in hospital emergency departments
  - Evaluation of reimbursement claims for patients transferred from an inpatient rehabilitation facility (IRF) to another facility that accepts Medicare or Medicaid patients

Hospitals (cont'd)

- Billing and Payment
  - Review of calculations of payments made to hospitals for new services and technologies
  - Prevention of inappropriate Medicare payments for beneficiaries with other sources of coverage
  - Review of hospital incidences of and CMS processes for preventing payments for "never events"
  - Examination of whether bad debts claimed by hospitals and other providers were appropriate under Medicare laws and regulations

Hospitals (cont'd)

- Enhanced Reimbursement Eligibility
  - Examine the impact of provider-based status for inpatient and outpatient facilities, including physician practices
  - Review whether hospitals accepting elevated Critical Access Hospital (CAH) and Disproportionate Share Hospital (DSH) payments meet the CAH and DSH designation criteria and conditions of participation

Hospitals (cont'd)

- Data Accuracy and Record Retention
  - Assess whether hospitals employ mechanisms to ensure the accuracy of data used to calculate wage indices for the inpatient prospective payment system (IPPS)
  - Evaluate hospitals' controls for ensuring the accuracy of quality of care data submitted for Medicare reimbursement
  - Examine Medicare payments to organ procurement organizations (OPO) to ensure that they are supported by adequate documentation

Home Health Agencies

- Focus on coding accuracy and the appropriateness of services provided by home health agencies (HHA)
- Examine payments for therapy and insulin injections to determine whether the services were adequately supported
- Review “potential aberrant billing” for HHA services ordered by referring physicians

Nursing Homes

- Review of RUG assignment and MDS completion
- Evaluation of potential misuse of antipsychotic drugs as an inappropriate chemical restraint
- Examination of the coding of mental health services in Part B outpatient claims
- Review of billing practices related to consolidated billing and submission of no-pay bills

Hospice Care

- Review of the nature and extent of hospice services provided to Medicare beneficiaries
- Assessment of billing for physician services provided to hospice patients, which are eligible for reimbursement under either Part A or Part B

Physicians and Other Health Professionals

- Coding practices
  - Review of services billed using procedure codes not found in the Healthcare Common Procedure Coding System
  - Review whether proper coding of location of services provided in ambulatory surgical centers (ASC) and hospital outpatient departments occurred
  - Review of whether clinical laboratories have inappropriately unbundled tests to increase payments
  - Examination of bills for services that are not covered by Medicare (indicated by the GY modifier) to evaluate the impact on beneficiaries

Physicians and Other Health Professionals

- Billing and Payment
  - Review of actual physician expenses by specialty to determine the accuracy of Medicare payments
  - Analysis of industry trends in the use of evaluation and management (E&M) services (e.g., long-distance physician claiming face-to-face visits; E&M services as part of a global surgery fee)
  - Review of appropriateness of Medicare payments for sleep studies
  - Assessment of high utilization of ultrasound services
  - Analysis regarding procedures performed at independent diagnostic testing facilities (IDTF)
  - Physician reassignment of right to bill

Durable Medical Equipment and Supplies

- Payments for DME
  - Verification that DME, prosthetics, orthotics, and supplies (DMEPOS) claims are reasonable and necessary
  - Review of the appropriateness of payments for repair and servicing of capped rental DME
  - Review of the sufficiency of supporting documentation for payments to DME suppliers that submitted claims with modifiers
- DME Categorization
  - Review of the appropriateness of current DME categorization to determine whether DME items are properly classified in association with current payment methodologies

Durable Medical Equipment and Supplies (cont'd)

- Part B and DME-related Services Provided to Nursing Home Residents
  - OIG will review
    1. The extent to which Part B services are provided to nursing home residents whose stays are not paid for under Medicare's Part A SNF benefit, with a focus on avoiding double billing
    2. Medical necessity, adequacy of documentation, and coding accuracy of claims submitted under Part B for enteral nutrition therapy (ENT)
    3. Part B pricing of enteral nutrients used in ENT

Durable Medical Equipment and Supplies (cont'd)

- Comparative Pricing Reviews
  - Similar comparative pricing reviews for negative pressure wound therapy pumps and power wheelchairs
- Error Rate Analysis
  - Review of CMS' determination of the DME error rate for 2008 and CMS' response to corrective actions that the OIG recommended regarding the 2006 DME error rate

ESRD-Related Initiatives

- Reviews related to Part A and Part B will address the use of ambulances to transport end stage renal disease (ESRD) beneficiaries to and from dialysis
- Review of Part C's reimbursement for services related to beneficiaries with ESRD

Medicare Part A and Part B Contractor Operations

- Evaluation of Various Contractors' Performance
  - Recovery audit contractors (RACs)
    - CMS oversees the efforts of RACs, who are tasked with identifying underpayment and overpayments by Medicare and implementing measures that will prevent improper payments
  - Medicare and Medicaid Data Match Project (Medi-Medi) contractors
    - OIG will review CMS' oversight of the Medi-Medi contractors who are responsible for matching Medicare and Medicaid data to identify health care programs' vulnerabilities
  - Program Safeguard Contractors (PSCs)
    - The PSCs perform investigative work on Medicare payments to identify and deter fraud and abuse, and identify any overpayments to Medicare claims processors for collection

Medicare Part A and Part B Contractor Operations (cont'd)

- National Provider Identifiers
  - Assessment of the accuracy and completeness of the National Provider Identifiers (NPIs)
- Consumer-Focused Assessments
  - Review of beneficiaries' use and understanding of Medicare Summary Notices (MSNs)
  - Review of CMS' handling of complaints referred by OIG from callers to the 1-800-HHS-TIPS hotline

Medicaid Issues

- Overpayment Issues
  - Review overpayment to providers, including independent laboratories and hospitals
- Enrollment of Excluded Medicaid Providers
  - Assess States' processes for enrolling health care providers, especially those subsequently excluded from federally funded health care programs
- Demonstration Projects
  - Evaluate demonstration projects to determine whether services are being provided in accordance with the conditions of the original project approval

Questions?