Life & Health

Health Care Communiqué

MARCH 2013

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For Medicare Advantage and Prescription Drug Programs

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2013 OIG Work Plan for Medicare Advantage and Prescription Drug Programs

OIG released its fiscal year 2013 work plan in early October. (The OIG fiscal year starts on October 1, 2012 and runs through September 30 2013.) This annual work plan provides a description of the activities that OIG will initiate or continue with in the oversight of the programs and operations of HHS. OIG's operational mission is to:

- Protect program integrity and the well-being of program beneficiaries by detecting and preventing fraud, waste and abuse;
- Identify opportunities to improve program economy, efficiency and effectiveness;
- Hold accountable those who do not meet program requirements or who violate Federal laws.

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OIG conducts audits, evaluations and investigations, provides guidance to the industry and when appropriate, imposes civil monetary penalties (CMP), assessments and administrative sanctions.

The majority of OIG's resources are directed toward safeguarding the integrity of the Medicare and Medicaid programs and the health and welfare of their beneficiaries. OIG's annual actions often result in changes to the Medicare Advantage and Prescription Drug programs based on recommendations made by OIG to CMS.

OIG has a number of initiatives lined up for both Medicare Advantage and the Prescription Drug Program.

Let's Take a Look:

OIG's Part C and Part D Initiatives for Fiscal Year 2013

Part C Medicare Advantage and Part D Prescription Drug Plans

- Benefit Integrity Activities of CMS Contractors for Part C and D

  OIG plans to review the benefit integrity activities performed by the National Benefits Integrity (NBI) program contractor. As you know, CMS contracted with NBI to perform its benefit integrity activities in 2010 for the Part C and D programs.

Part C Medicare Advantage

- Special Needs Plans – CMS Oversight of Enrollment and Special Needs Plans

  OIG plans to review CMS' oversight of MA plans' enrollment practices and determine whether chronic-care SNPs are complying with CMS enrollment requirements.

- Provision of Services – Compliance with Medicare Requirements

  OIG plans to review MAO oversight of subcontractors that provide enrollee benefits such as prescription drugs and mental health services. OIG will review the oversight and monitoring activities of MAOs,

determine compliance with regulations and examine the processes used to ensure that subcontractors are meeting their contractual obligations.

- Beneficiary Appeals – Beneficiary Requests for Reconsideration of Denied Services or Payments
  OIG plans to review denial notices for services or payments that MAOs sent to beneficiaries to determine whether the notices clearly explained the rights to request a reconsideration and to appeal the determination. OIG also plans to examine the differences between denials of services and payments for which beneficiaries did and did not choose to appeal. (It is interesting to note that a prior OIG report found that fewer than 1 in 10 beneficiaries requested reconsiderations when their MAO denied their requests for medical services.)
- MAO Bid Proposals – CMS Oversight of Data Quality and Accuracy
  OIG will assess the CMS methodology (both desk review and quality) for ensuring that MA bids are accurate. Work will be performed to ensure that issues identified by CMS during the bid process are appropriately addressed by MAOs prior to bid approval.
- Encounter Data – CMS Oversight of Data Integrity
  OIG will review the extent to which CMS verifies that MA encounter data is complete, consistent and accurate.
- Risk Adjustment Data – Sufficient Documentation To Support Diagnoses
  OIG will determine whether the diagnoses that MAOs submitted to CMS for use in risk score calculations complied with Federal requirements. OIG will review medical record documentation to ensure that the documentation supports the submitted diagnoses.
- Risk Adjustment Data – Accuracy of Payment Adjustments
  OIG will review whether CMS properly adjusted payments to MA plans based on the outcomes of its data validation reviews.
- Risk Adjustment Payments – MAOs that offer Prescription Drug Plans
  OIG will review supporting data for beneficiary diagnosis codes submitted by MAPDs. OIG will determine the accuracy of the data, the validity of the diagnosis codes, the accuracy of the risk score and the risk-adjusted monthly payments.
- Reporting Requirements – CMS Quality Oversight of MAO Reporting
  OIG will review CMS' efforts to ensure that MAOs comply with Part C reporting requirements and to improve the quality of the reporting requirements data. OIG will also review how CMS uses the data to monitor, assess and improve MAO performance.

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Part D Prescription Drug Program

- **Program Integrity** – Beneficiary Use of Manufacturer Copayment Coupons
  OIG will review the safeguards that Pharmaceutical manufacturers have in place to ensure that beneficiaries do not use copayment coupons to obtain prescription drugs paid for by Part D. The use of copay coupons in Federal health programs implicates the anti-kickback statute.
- **Program Integrity** – Voluntary Reporting of FWA by Plan Sponsors
  OIG will review the extent to which Part D plan sponsors have voluntarily reported Part D antifraud activity data to CMS since 2010. OIG has indicated that little is known about the potential fraud and abuse identified by Part D plan sponsors at this time.
- **PBMs** – Part D Sponsors Oversight of PBMs' Administration of Plan Benefits
  OIG will assess the ability of Part D sponsors to oversee how their PBMs carry out their responsibilities to administer sponsors' formularies and manage prescription drug use.
- **Patient Safety and Quality of Care** – Part D Drugs Approved and Registered by FDA
  OIG will determine whether drugs used in the Part D program have been found to be safe and effective by the FDA and whether Part D beneficiaries were dispensed only drugs that the FDA has deemed safe and effective.
- **Drug Payments** – Specialty Tier Formularies and Related Cost Sharing
  OIG will analyze the variation in PDPs' specialty tier formularies and beneficiary cost sharing requirements.
- **Drug Payments** – Characteristics Associated with Atypically High Billing
  OIG will review Part D drugs billed in 2009 to identify characteristics of associated prescribers and beneficiaries to determine whether there are trends or other patterns in common.
- **Drug Payments** – Part D Claims Duplicated in Part A and Part B
  OIG will review Part D claims to determine whether they were duplicated in Part A/B and whether they were correct and supported.
- **Drug Payments** – Questionable Claims for HIV Drugs
  OIG will review HIV drugs billed in 2010 to ensure they were billed for medically accepted indications.
- **Drug Payments** – Drugs Dispensed Through Retail Pharmacies with Discount Generic Programs
  OIG will determine whether the Part D program is receiving the discount drug prices available at certain retail pharmacies if the sponsor is contractually entitled to the discount. The review will determine the number of claims paid above the discount and the dollars associated with these claims.

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- **Coverage Gap** – Quality of Sponsor Data Used in Calculating Coverage-Gap Discounts
  OIG will review data submitted by Part D sponsors used in the calculation of the coverage gap discount. OIG will review the accuracy of sponsor submitted data to ensure that beneficiary payments are correct and that amounts paid to sponsors are supported.
- **Coverage Gap** – Accuracy of Sponsors' Tracking TrOOP
  OIG will review the accuracy of Part D sponsors' tracking of TrOOP costs by reviewing adjustments to pharmacy claims data on Part D prescriptions and the effect on beneficiaries' TrOOP expenses that qualify to be included to meet thresholds for catastrophic coverage.
- **PDE** – Data Submitted for Incarcerated Individuals
  OIG will review PDE data to determine whether sponsors submitted data for incarcerated individuals and whether CMS accepted the data.
- **Sponsors' Bid Proposals** – Documentation of Administrative Costs
  OIG will review the documentation provided by Part D sponsors to support administrative costs submitted in the annual bid proposals to CMS.
- **Sponsors' Bid Proposals** – Documentation of Investment Income
  OIG will review the documentation provided by Part D sponsors to support investment income submitted in the annual bid proposals to CMS.
- **Reconciliations of Payments to Sponsors** – Discrepancies Between Negotiated and Actual Rebates
  OIG will review negotiated rebate amounts between Part D sponsors/PBMs and pharmaceutical manufacturers with the actual rebates paid and analyze any discrepancies.
- **Reconciliation of Payments to Sponsors** – Reopening Final Payment Determinations
  OIG will review the CMS processes for reopening final payment determinations including the data received and CMS policies, procedures and instructions.
- **Risk Sharing and Risk Corridors** – Savings Potential of Adjusting Risk Corridors
  OIG will analyze risk-sharing payments between the Federal Government and Part D sponsors to determine whether cost savings could have been realized had the existing risk corridor thresholds remained at 2006/2007 levels. CMS has the authority to retain existing risk corridor thresholds or widen them for plan year 2012 and beyond.
- **Information Systems** – Supporting Systems at Small and Medium Size Plans and Plans New to Medicare
  OIG will review the implementation of systems that support prescription drug benefit plans and the expansion of beneficiary choices at MA plans, small to medium size Part D sponsors and other Part D sponsors with little or no previous involvement in the Medicare program. OIG will evaluate the controls to support the systems' functions, the plans' compliance with Part D contractual requirements, CMS regulations and CMS instructions for systems supporting key Part D contractual requirements (e.g., enrollment, COB, TrOOP and PDE).

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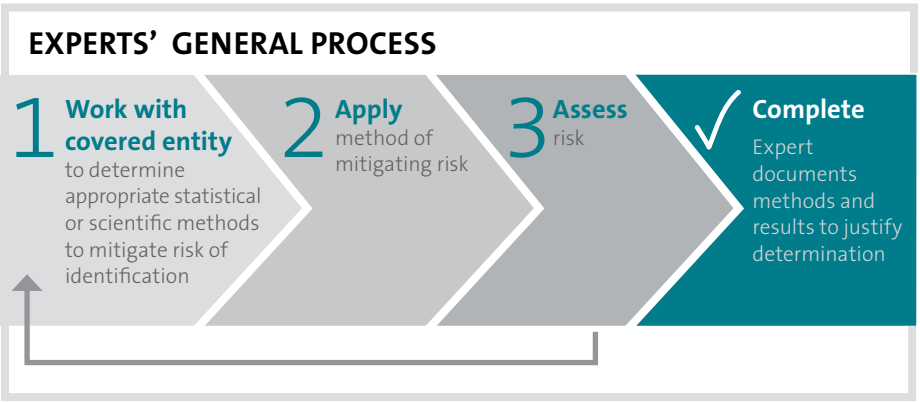
HIPAA: De-identifying Data

On November 26, 2012 the Office of Civil Rights (OCR) released long awaited guidance on de-identifying data. They did this in the form of a white paper and not regulations. The guidance answered some questions, but left others open.

Health care organizations are able to protect patient privacy by removing or limiting information that identifies or can be used to identify them, under the HIPAA Privacy Standards, through de-identification. This can be done through two methods – removal of 18 types of identifiers (Safe Harbor) or obtaining an expert determination – the Expert Determination method.

Until this guidance most organizations that needed to address this issue used the Safe Harbor method and removed the 18 data elements. OCR did provide additional guidance related to use of three digit zip codes, dates and free form text fields.

In explaining the Expert Determination method OCR did not specify the requirements to be an expert or what process an expert should follow. Covered entities should be prepared to support their decisions when selecting and relying on an expert. OCR has also not defined the meaning of "very small" as contained in the Privacy Rule, so covered entities should be prepared to share their experts' determinations regarding their belief that a risk is "very small".



Some of the factors an expert would consider when assessing risk are:

- **Replicability** – Prioritize health information features into levels of risk according to the chance it will consistently occur in relation to the individual.
- **Data Source Availability** – Determine which external data sources contain the patients' identifiers and the replicable features in the health information, as well as who is permitted access to the data source.
- **Distinguishability** – Determine the extent to which the subject's data can be distinguished in the health information.
- **Assess Risk** – The greater the replicability, availability, and distinguishability of the health information, the greater the risk for identification.

Safe Harbor Elements

1. Names
2. Geographic subdivisions smaller than a state
3. All elements of dates, except year
4. Telephone numbers
5. Fax numbers
6. Email addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/licenses numbers
12. Vehicle identifiers and serial numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) addresses
16. Biometric identifiers
17. Full-face photographs
18. Any other unique identifying number, characteristics or code

When evaluating identification risk, an expert often considers the degree to which a data set can be linked to a data source that reveals the identity of the corresponding individuals. An important aspect of identification risk assessment is the route by which health information can be linked to naming sources or sensitive knowledge can be inferred. An expert may apply generally accepted statistical or scientific principles to compute the likelihood that a record in a data set is expected to be unique, or linkable to only one person, within the population to which it is being compared.

Medicare Advantage Contract Amendment

On October 5, 2012 CMS released a Medicare Advantage (MA) Contract Amendment, which provides contract language for Medicare Advantage Organizations (MAOs) to use in provider and administrative agreements between an MAO and its first-tier entity or between a first-tier entity and its downstream entity.

This contract amendment can be used as a bilateral or unilateral amendment to contracts with health care providers and facilities and with administrative contractors. It complies with Medicare laws, regulations, and CMS instructions, including, but not limited to, the Medicare Prescription Drug, Improvement and Modernization Act of 2003. The CMS release indicated the amendment is not appropriate for use in Medicare Part D prescription drug contracts, Medicare/ Medicaid Plans, or any other contracts distinct from MA products.

Use of this contract amendment is voluntary. CMS does strongly encourage MAOs to use this contract amendment for new and existing contracts or letters of agreement as a way to facilitate the MA contracting process. While not stated in the CMS release notice it seems reasonable that the amendment if used as released would not be subject to CMS audit findings.

Final Part C EOB

On October 12, 2012 CMS released the final Part C EOB. The intent is to require the use of this model document by October 1, 2013. While Part D has had a standard in this area for a while, this is a new requirement for Part C. Compliance with this requirement could result in substantial system changes for some health plans.

Health plans can choose to:

1. Send members an EOB each month by the end of the month following the month in which members' claims for medical and supplemental benefits were processed, using model language; or
2. Send members an EOB for each claim as well as quarterly and annual summary EOBs. The quarterly EOBs would be sent at the end of the month following the calendar year quarter in which claims were processed (i.e., January 1-March 31, April 1-June 30, July 1-September 30, and October 1-December 31).

UL's "HIPAA: Privacy Standards" course will include the new guidance.

The model template includes five sections:

Section 1: Detailed claims information for medical and hospital care, including monthly and yearly totals for out-of-pocket (OOP) spending.

Section 2: Detailed claims information for optional supplemental benefits, including monthly and yearly OOP spending totals. (Note: if the plan counts spending on optional supplemental benefits as part of the maximum out-of-pocket cost (MOOP) limit, those claims would be included in section 1; thus, this section would be eliminated and the other sections renumbered accordingly.)

Section 3: A statement regarding plan deductibles and description of the plan's MOOP limit, including an accounting of the dollar amount the beneficiary has spent in relation to the total plan deductible and MOOP.

Section 4: A reminder about Medicare preventive services.

Section 5: An optional section that may be used by the MA organization to communicate plan-specific benefits and costs.

The CMS notice included nine attachments with the specification details.

Health Care Communiqué Authors

The content in this newsletter has been provided by Monica DeRosa and Albert Walker, who are Partners with Pelorus Management Consultants (PMC).

PMC serves as the subject matter experts for a number of UL's Medicare, HIPAA and compliance courses.

They also work with many Medicare and Medicaid health plans on a range of issues including start-up, expansion, training, CMS mock audits, corrective action plans, proposal responses and regulatory interaction. They are currently working with their clients to implement many of the health care reform tasks that need to be addressed over the next several years. This includes helping a number of clients expand to new areas and offer new products (i.e., RFP responses, certificates of authority applications.)

More information regarding PMC LLC may be obtained from the PMC web site: www.pmcinfo.com, or by sending an e-mail to Monica@pmcinfo.com or Albert@pmcinfo.com or calling 973.992.2626.

About UL

UL is a premier global independent safety science company. UL develops technology-enabled knowledge solutions for helping to assure regulatory compliance and improve business performance. For more than 30 years, the company has served corporate and government clients in the Life Science, Health Care, Energy and Industrial sectors using our award-winning learning management platforms, unique regulatory and business content and professional services.

CMS Calendar

March 1	Initial Submission deadline for risk adjustment data with dates of service January 1, 2012 through December 31, 2012
March 26	Release of the HPMS formulary submissions module
Ongoing	CMS Audits
Ongoing	OCR HIPAA Audits