



HEALTH CARE COMMUNIQUÉ

Q3 2015

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CMS ANNOUNCES TWO PILOT AUDIT PROGRAMS FOR 2015



On February 13, 2015, CMS released their 2015 Audit Program Protocols and Process Updates. Included in their communication was the announcement that two pilot audits would be added in 2015. The pilot audit programs that CMS is adding are Medication Therapy Management (PILOT) and Provider Network Adequacy (PILOT). This article summarizes of each pilot program.

Medication Therapy Management (PILOT)

CMS requires that all Medicare Part D plans implement a Medication Therapy Management (MTM) program. The goal of an MTM program is to ensure that targeted beneficiaries optimize outcomes by evaluating and improving the medications that are being utilized and to reduce the potential for any adverse events. CMS' objective in adding this to their program audit is to:

1. Determine and assess if a Medicare Part D plan's MTM program complies with 42 CFR § 423.153(d) and with all MTM specific guidance that has been released by CMS.
2. Highlight any deficiencies with a plan's MTM program and require the plan to make the needed corrections.
3. Impose enforcement actions and/or identify potential performance measures that a plan can implement.

Provider Network Adequacy (PILOT)

CMS requires that all Medicare Part D plans maintain a provider network that is adequate. The provider network must ensure that members have access to specialty and sub-specialty providers. The addition of this program audit area will be to:

1. Determine the adequacy of a plan's provider network.
2. Review the standards for accessibility of the plan's provider network and ensure that providers within the network are accepting and treating enrollees.

CMS is adding these two pilot audit programs in the middle of 2015. Pilot program audits in 2015 will not be counted against a plan's overall program audit score. In addition, pilot audit scores will not be included in the final CMS Program Audit report and the pilot area scores will not be posted to CMS' website. CMS has not yet released specifics on data requirements for these pilot program audits. For those plans who receive a pilot program audit in 2015, CMS is encouraging feedback. The MTM and Provider Network Adequacy pilots will be fully incorporated into the 2016 CMS Program Audit and at that point will count in a plan's total audit score.



HOW SPECIALTY DRUGS ARE CLASSIFIED

Specialty drugs are the fastest growing component of prescription drug expenditures because of enormous increases in availability and use, coupled with drug cost inflation. This course covers the proactive management of specialty medications in order to help payers control costs and maximize the value of these therapies.

Generally, specialty drugs are very expensive (e.g., Medicare Part D defines a specialty drug as any product in which the negotiated monthly allowed price is \$600 or more) and usually possess one or more characteristics:

Uses Biotechnology – a drug product developed using biotechnology and made from proteins, nucleic acids, or living organisms (e.g., biologics) may be considered a specialty drug.

Treats a Chronic, Complex, or Life-threatening Condition – a drug product used for treatment of a rare or common condition that is chronic, complex, or life-threatening in nature may be considered a specialty drug; conditions managed with specialty drugs include blood disorders, cancer, growth hormone deficiency, hepatitis, multiple sclerosis, rheumatoid arthritis, and other autoimmune disorders.

Requires Patient Training – a drug product that requires individualized patient training on drug administration, including supplies and devices, may be considered a specialty drug. Monitoring for adherence, case management, and patient education are critical.

Requires Coordination of Care – a drug product that needs coordination of care when beginning and/or during therapy may be considered a specialty drug.

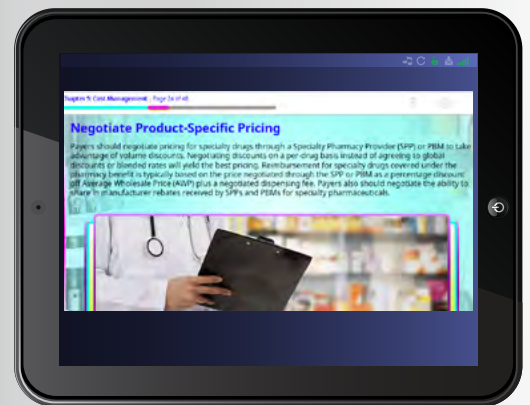
Requires Tracking and Follow-up – a drug product that requires tracking and follow-up for patient medication compliance and in which safety is crucial for success of therapy may be considered a specialty drug. For example, periodic lab work and diagnostic testing are necessary to monitor patient response to therapy and potentially serious side effects.

Requires Special Handling, Shipping, and Storage – a drug product that requires special handling, shipping, and storage may be considered a specialty drug. For example, special transportation and storage often are required for refrigeration and timely delivery to clinicians and patients.

Has Restricted Access/Limited Distribution – a drug product that has restricted access or limited distribution (e.g., a designated specialty pharmacy) may be considered a specialty drug.

Note: This article is an excerpt from our new course, “Introduction to Specialty Pharmacy Management,” (Code: GHC06). Subscribers to our [General Health Care Library](#) have already received this eLearning course on their instance of ComplianceWire.

If you are not a subscriber, contact Terry Hughes at terry.hughes@ul.com for more information about this course.



About UL's New Specialty Pharmacy Course:

The new course, written by the experts at Solid Benefit Guidance, focuses on Drug Spend, Strategies, Cost Management, Utilization Management, Clinical Care Management and Selecting a Provider.

After completing this course, learners will be able to identify the major types of specialty pharmacy drugs and how they are administered to patients. Learners will also be able to recognize the costs of specialty pharmacy therapies and their impact on drug expenditures.

Learners will also be able to recognize the difference in managing specialty drugs in the medical and drug benefit. You will be able to identify strategies for controlling costs of specialty pharmacy drugs as well as identify approaches for managing utilization of specialty pharmacy drugs. Finally, you will be able to recognize the criteria for selecting a specialty pharmacy provider.



PRESCRIBER VALIDATION UPDATE

On June 1, 2015, CMS released updated prescriber enrollment guidance to supplement the Interim Final Rule (IFC) released on May 6, 2015, which made changes to the Final Rule. The new guidance, titled “Medicare Part D Prescriber Enrollment Requirement Update,” outlined additional requirements, clarification of previous requirements, and new deadlines for enforcement of prescriber enrollment. The memo also included additional information on the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and how that law and the new IFC might interact.

The IFC’s effective date is June 1, 2015, and the revised prescriber enrollment in Medicare requirement’s effective date is January 1, 2016; however CMS is delaying the enforcement of the requirement until June 1, 2016. CMS’ delay in enforcement is to minimize the potential disruption to beneficiaries’ access to Part D medications and to not compromise continuity of care. CMS strongly encourages prescribers to submit their Medicare enrollment applications or opt-out affidavits to their Medicare Administration Contractors (MACs) before January 1, 2016.

MACRA requires that for plan year 2016 and thereafter, claims for covered Part D drugs must include a valid prescriber NPI. Therefore, a Part D sponsor cannot pay a claim that is determined not to have an active and valid prescriber NPI, unless the pharmacy corrects the NPI or confirms that it is active and valid. Once the prescriber enrollment is enforced on June 1, 2016, this verification process would only apply to “Other Authorized Prescribers,” since they are now exempt from this requirement. CMS is to provide a list of specialties for this category at a later date.

Additionally, MACRA also requires that when a claim for a Part D drug is not paid because it does not contain an active valid NPI that the affected beneficiary be properly informed at point of service. CMS is developing these notification procedures and will provide additional guidance to Part D sponsors in the near future.

The IFC also included provisions requiring Part D sponsors to cover a three-month provisional supply of the drug and provide the member with an individualized written notice before denying a Part D claim, in the event the member’s prescriber is not enrolled in Medicare or does not have an opt-out affidavit on file. The three-month provisional supply is intended to give prescriber time to enroll or opt-out. CMS will be providing additional guidance in the future.

CMS strongly encourages Part D sponsors to work collaboratively with their PBMs to initiate outreach activities to prescribers no later than January 1, 2016. Outreach activities will enhance CMS’ outreach and prescriber enrollment trends and will help in mitigating potential member impact. CMS will be releasing additional information on outreach activities.

The IFC will be posted on the CMS Part D Prescriber Enrollment website at: <http://www.cms.gov/Medicare/Prescription-DrugCoverage/PrescriptionDrugCovGenIn/Prescriber-Enrollment-Information.html>.

Part D sponsors, PBMs and pharmacies should periodically check this website for updates and additional information.



2015 MMP CALL CENTER STUDY: MONITORING AND GUIDANCE FOR ACCURACY

On June 15, 2015, HPMS released a memo entitled, "2015 MMP Call Center Monitoring and Guidance for Accuracy Study." CMS has contracted with IMPAQ International, LLC to perform the call center monitoring for all active MMPs during 3rd quarter 2015. The memo defines the sections of the study and offers tips to assist MMP organizations in how to better improve their results.

By June 30, 2015, all MMPs were required to review and update their prospective enrollee toll-free beneficiary call center phone numbers and TTY/TDD numbers in Health Plan Management System (HPMS). The phone numbers are obtained from HPMS on a bi-weekly schedule and updated with IMPAQ International, LLC automated dialing software. If the MMP attains poor findings on the measure as a result of inaccurate phone numbers, the monitoring findings will not be refuted.

Accuracy Study: This study will measure MMPs' Part C and Part D toll-free prospective enrollee call center phone lines and TTY phone lines to determine the accuracy of plan information supplied by customer service representatives (CSRs). Compliance action will be taken when an MMP organization's rate of accuracy in answering questions is below 75%.

Compliance actions could additionally be taken when an MMP organization is also an outlier with respect to other MMP sponsors or so far below CMS' reasonable expectations that notice to the MMP organization is warranted in order to ensure that the organization provides prospective enrollees with the services to which they are permitted. Areas consist of but are not limited to, inappropriate call center closures (i.e., closed during business hours) and failure to maintain a toll-free telephone number for an organization's prospective enrollees.

CMS will provide complete results to the Compliance Officer via a letter emailed to them for each associated contract ID. Upon request, CMS will provide call detail files, and will consider challenges to the data for miscalculations or the use of incorrect data sets (i.e. completed instead of successful calls); CMS will not contemplate disputes based on Part D Sponsors' internal monitoring outcomes.



FRAUD UPDATE

Early in July, the Office of Inspector General (OIG) of Health and Human Services released two reports on the continued fraud and abuse to Medicare's popular prescription drug program, Part D. The release of the reports follows the arrests of 44 pharmacy owners, doctors and others.

Part D provides drug coverage for 39 million seniors and disabled people; the overall cost in 2014 was \$121 billion. The OIG has previously reported on lack of oversight by the Centers for Medicare and Medicaid Services (CMS) for failure to conduct adequate oversight of doctors, pharmacies and beneficiaries.

The first report covered data from last year:

- 1400 pharmacies had questionable billing practices, either high numbers of prescriptions/patient or high proportion of narcotic controlled substances.
- Prescriptions for commonly abused opioids continue to increase. Over 40% of Medicare beneficiaries in Alabama, Alaska, Oklahoma and Tennessee filled at least one prescription for a narcotic in 2014, compared to 32% for the nation as a whole.
- New York and Los Angeles maintain to be hot spots for questionable prescribing having a much higher use of expensive drugs associated with fraud than other parts of the country.

The second report outlined the need for Medicare to implement reforms around fraud which they have so far resisted which included:

- Require health plans to report ALL potential fraud and abuse to CMS and fraud monitoring contractors. Currently, reporting is voluntary. In 2014, less than 50% of Part D insurers reported potential fraud and abuse.
- Include other drugs beyond controlled substances for review of potential fraud and abuse.
- Implement patient restriction programs on patients suspected of doctor shopping. This is frequently used by Medicaid and private insurance companies.

DISCLAIMER LANGUAGE FOR PLANS WITH LIMITED ACCESS TO PREFERRED COST-SHARING

The Final CY 2016 Call Letter outlined the requirement for all Part D Sponsors with preferred cost-sharing pharmacies to conduct a network analysis to determine if access to preferred cost-sharing pharmacies in their network falls below the published access outlier thresholds. Should a Part D Sponsor identify that their 2016 network falls below these thresholds, they must make disclosures on 2016 marketing materials.

The below disclaimer will be required but not limited to the following marketing materials: the Summary of Benefits, Annual Notice of Change, Evidence of Coverage, Pharmacy Directory, websites and all print, television and radio advertisements that reference preferred cost-sharing or preferred cost-sharing pharmacy networks.

"<insert organization/plan name>'s pharmacy network offers limited access to pharmacies with preferred cost-sharing in <insert geographic area type(s) and state(s) for which plan is an outlier>. The lower costs advertised in our plan materials for these pharmacies may not be available at the pharmacy you use. For up-to-date information about our network pharmacies, including pharmacies with preferred cost-sharing, please call <insert Member Services phone number and TTY> or consult the online pharmacy directory at <insert website>."





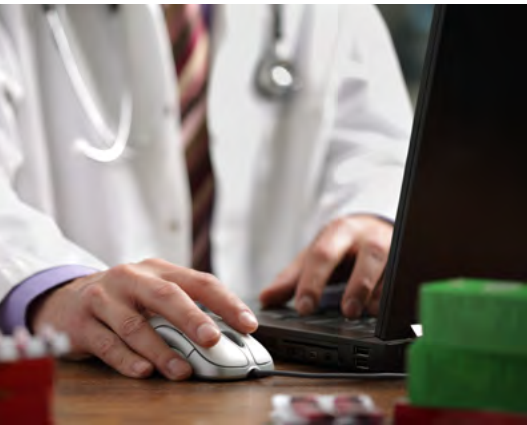
CMS TIMELINE

August 1, 2015	Plans expected to submit model Low Income Subsidy (LIS) riders in HPMS
August 20-24, 2015	CY 2016 preview of the 2016 Medicare & You plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs)
August 26-28, 2015	First CY 2016 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS MPF only.
August 28, 2015	Registration deadline for in-person attendance for CMS Fall Conference.
August 31, 2015	2016 MTM Program Annual Review completed
Late August 2015	Contracting Materials submitted to CMS
End of Aug./Early Sept.	Plan preview periods of Star Ratings in HMPS
Sept. 8-11, 2015	Second CY 2016 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HMPS
Sept. 10, 2015	CMS 2015 Medicare Advantage and Prescription Plan Fall Conference and Webcast
Sept. 16-30, 2015	CMS mails the 2016 Medicare & You Handbook to Medicare beneficiaries
Sept. 23, 2015	Deadline for Part D. Sponsors, cost-based, MA and MA-PD organizations to request a plan correction to the plan benefit package (PBP) via HPMS.



CMS TIMELINE CONT.

Sept. 30, 2015	<p>The following documents are due to current enrollees:</p> <ul style="list-style-type: none">• Standardized Annual Notice of Change/Evidence of Coverage (ANOC/EOC) for all MA, MA-PD, PDP, and cost-based plans offering Part D.• Standardized ANOC with Summary of Benefits for D-SNPs and MMPs that choose to separate the ANOC from the EOC.• Abridged or Comprehensive formularies• LIS rider• Pharmacy/Provider directories <p>The multi-language insert should be sent with ANOC/EOC and the SB.</p> <p>The documents identified above are the only documents permitted to be sent prior to the October 1, 2015 deadline.</p>
Mid October, 2015	<p>Release of the online CY 2017 Notice of Intent to Apply for a new Contract or Contract Expansion (MA, MA-PD, PDPs and “800 series” EGWPs and Direct Contract EGWPs).</p>
October 1, 2015	<p>Organizations may begin marketing their CY 2016 Plan benefits.</p> <p>*Note: Once an organization begins marketing CY 2016 plans, the organization must cease marketing CY 2015 plans through mass media or direct mail marketing (except for age-in mailings). Organizations may still provide CY 2015 materials upon request, conduct one-on-one sales appointments, and process enrollment applications.</p>
October 1, 2015	<p>Tentative date for 2016 plan and drug benefit data to be displayed on Medicare Plan Finder on Medicare.gov (not applicable to EGWPs).</p>



About UL EduNeering

UL EduNeering is a business line within UL Life & Health's Business Unit. UL is a premier global independent safety science company that has championed progress for 120 years. Its more than 10,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council, and the Duke Clinical Research Institute.



About SBG

Solid Benefit Guidance, LLC (SBG) is one of the nation's leading consulting firms and thought leaders in the PBM industry. With more than 130 years of collective experience in this highly complex industry, SBG provides plan sponsors and health plans an unparalleled evaluation of their compliance, pharmacy costs, performance and trends. Some of the services they offer include:

- PBM Procurement & Vendor Oversight
- Compliance Medicare/Medicaid
- PBM Auditing
- Specialty Pharmacy Management Strategy
- Clinical Consulting

SBG experts serve as UL EduNeering's Health Care Library Course authors, and also contribute articles to the Health Care Communiqué.