Life & Health

Health Care Communiqué

Q2 2015

2015 CMS AUDIT PROTOCOL HIGHLIGHTS

On February 12, 2015, CMS issued the 2015 CMS Audit Protocols via HPMS. This is the earliest that CMS has issued the protocols and there were significant changes. SBG has reviewed the protocols and universe templates in their entirety and summarized the changes, which may impact your Plan.

Overview:

- New Audit Selection Methodology – CMS will utilize the same risk-based analysis, but will focus on sponsors that have never been audited, sponsors new to a program (in first 2 years with no previous Medicare experience) or sponsors that represent a large percentage of MA or Part D enrollment.
- MMP – CMS will be adding MMP contracts to these audits and coordinate with the applicable States.
- P & T Review – Removed for 2015.
- Timeliness review in ODAG and CDAG – Universes are still being reviewed for timeliness. However, the universes have been modified to assist with tracking by request type. This revision resulted in a significant increase in the number of universes and samples requested.

(continued...)

- **Compliance Program Effectiveness** – CMS is streamlining this process; less documentation is required up front from the Plan. CMS will trace how an issue was resolved based upon the 7 elements. CMS will select 5 Tracer samples for this section. Interviews with Plan staff will still be conducted using the interview guides, which have also been streamlined.
- **New Audit Protocols** – Will be rolled out in mid-2015.
  - **MTM and Provider Network Adequacy** – These protocols will pilot in 2015, but will be added to the audit protocols in 2016 and will be counted toward the overall audit score for the sponsor.
- **Timing** – Sponsors will receive the audit notice 6 weeks prior to the audit which is 2 weeks earlier than in the last few years. Universes will be due in 3 weeks, adding an additional week to the timeframes required in 2014. CMS has stated that the first audit letters for 2015 will be sent in April.
- **Universe Accuracy** – Sponsors will be given a total of 3 attempts to provide correct universes; this includes submissions prior to the audit and during the audit. If they need to submit more than 3 times, this will be considered an ICAR for each condition impacted by the universe (this is a significant risk). Additionally, if a universe cannot be pulled within the 3 week timeframe, it is mentioned in the guidance that this could result in an enforcement action. In 2016, CMS will add correct and timely universes as a scoring element to the audits. Any ICARs for issues with universe pulls will be validated as part of a validation audit, but may not need to be corrected within 72 hours per standard ICAR protocol.
- **Previously Disclosed vs. Self-Identified Issues** – CMS clarified these for audit and review purposes. As part of the audit, sponsors will list all items previously disclosed to CMS plus anything they identified in-house, but have not yet disclosed to CMS from 1/1/2015 until the date of the audit. Issues are due to CMS 5 business days after the engagement letter is received. Reports will need to include a full description of each issue, remediation steps taken and current status. CMS will also require for each issue a Beneficiary Impact Analysis (new template). CMS Account Managers will be asked to validate these issues. Sponsors will have 3 attempts to send this documentation correctly; CMS will use the last version of issues submitted for ODAG and CDAG, they must be sent prior to the universes being due for the audit.
  - **Corrected Issues** – CMS will consider an issue corrected if appropriate and adequate remediation has happened before the receipt of the audit notice. These will be validated as part of the audit. The issue will be included in the audit report as an observation and noted as corrected. It will not negatively impact the audit score. If the issue is still found, CMS will cite the issue for the applicable condition (CAR, ICAR) and it will be listed in the audit.
  - **Uncorrected Issues** – For uncorrected self-identified issues, CMS will cite the applicable condition (observation, CAR, ICAR) in the audit. They will not include these cases as audit samples to corroborate the issue. For uncorrected disclosed issues, CMS will not include these in the samples and the issue will appear in the audit report as an observation, if no other cases are identified. Any additional cases will be cited as an ICAR or CAR.
- **Beneficiary Impact Analysis Templates** – There is a new template from CMS that sponsors will be expected to fill out for disclosures as part of the audits.

CHANGES BETWEEN 2014 AND 2015 SAMPLES AND UNIVERSES:

Universes	CPE	CDAG	FA	ODAG	SNP	MTM	PA
2014	35	3	5	4	1	N/A	N/A
2015	5	15	4	13	2	Pending	Pending
Samples							
2014	N/A	55	90*	75	30 Cases	N/A	N/A
2015	5 Tracer	130	75	140	30 Cases	Pending	Pending

* 15 samples were for P & T which was removed in 2015.

For 2015, the total number of universes (excluding MTM and PA) is 39 and the total number of samples (excluding MTM and PA) is 380, which is a significant increase over 2014.

PERSPECTIVES ON BIOSIMILARS

On March 6, 2015, Novartis' filgrastim-sndz (Zarxio®) became the first biosimilar to be approved by the FDA in the United States. A biosimilar product is a biological product that is highly similar to an already-approved biological product, known as a reference product. The biosimilar must show it has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products. Zarxio® is considered to be a biosimilar for Amgen's Neupogen® (filgrastim), a biologic which has been available since 1991 and used to stimulate bone marrow production of more white blood cells (WBCs).

The approval of Zarxio® marks a great achievement in pharmaceutical technology and paves the way for the introduction of more biosimilars in the U.S. market. While spending on prescription medications continue to rise, along with double-digit trends in specialty Biologic medication, biosimilars will play an important part in the future of keeping healthcare benefits affordable by payers. Globally, biosimilars earned revenues worldwide of approximately $1.2 billion in 2013, with growth estimates of $24 billion by 2019.[7] The untapped U.S. market, along with a strong biosimilars pipeline, as well as markets in Asia-Pacific and Latin America with a low cost of manufacturing, will further enhance key growth opportunities for biosimilars. The overall biosimilar markets in countries (such as the U.S. and Japan) are also expected to grow exponentially, as regulatory bodies such as the FDA issue further clarity and guidance on the regulatory pathway for biosimilars and their interchangeability. As of March 2015, the FDA has accepted four total biosimilar applications.

PERSPECTIVES ON BIOSIMILARS *(Continued)*

Payer Considerations

While we anticipate that biosimilars will bring favorable market competition, their cost savings potential remains uncertain. Based on European experience, pricing behavior indicates that biosimilar discounts are typically less than 25 percent.[8] Pricing and cost savings depend mostly on the biosimilar manufacturer, who may not necessarily market their product at a lower price, but instead negotiate discounts with payers and PBMs in the form of rebates and/or other contractual arrangements to receive discounted prices. For payers who have contracted their rebates and pharmacy discounts for medications through a PBM, the degree of potential savings will depend on the structure of these arrangements.

Payers additionally need to keep in mind that biosimilars will be brand medications (not generics). Therefore, payers should ideally clarify this definition in their health plan contracts, or minimally in coverage policies.

BIOSIMILAR PIPELINE

Product Description	Potential Use(s)	FDA
Novartis' biosimilar version (Zarzio®) of: - Amgen's Neupogen®	White Blood Cell Stimulator in cancer patients and other chronic conditions that cause low white blood cells	7/24/2014
Celltrion's biosimilar version (Remsima™) of: - Johnson and Johnson's Remicade®	Rheumatologic Conditions	8/12/2014
Apotex's biosimilar version of: - Amgen's Neulasta®	White Blood Cell stimulator in cancer patients	12/23/2014
Hospira's biosimilar version (Retacrit™): - Amgen's Epogen® - Janssen's Procrit ®	Red Blood Cell stimulator in Anemia/End Stage Renal Disease	1/12/2015
Biosimilar for Amgen's Prolia®*	Osteoporosis	–
Biosimilar for Abbvie's Humira®*	Rheumatologic Conditions	–
Biosimilar for Genentech's Actemra®*	Rheumatologic Conditions	–
Biosimilar for Janssen's Simponi®*	Rheumatologic Conditions	–
Biosimilar for Genentech's Avastin®*	Various cancers	–
Biosimilar for Eli Lilly's Erbitux®*	Various cancers	–

* What is the *?

Pharmacy and Therapeutics (P & T) Committee Planning & Preparation

For payers who have an internal P & T Committee and maintain the formulary decision-making on products for coverage, considerations and planning for reviewing biosimilars should include updating their P & T Committee charter and defining processes for evaluating biosimilars as formulary options to assure consistent review methods and decision-making parameters. This includes:

- Determining whether coverage for the biosimilar should be the same, advantaged, or disadvantaged versus the innovator brand based on evaluating biosimilarity and interchangeability.
- Ensuring that the P & T Committee, in their evaluation of biosimilars, understands the definitions of "biosimilar", "biosimilarity", and "interchangeability" with respect to the reference innovator biologic. For example:

  "Biosimilar/biosimilarity" means that the biosimilar product:[10]
  - May have minor differences in clinically inactive components versus the reference innovator biologic.
  - Has no clinically meaningful differences in terms of safety, purity and potency compared to the reference innovator biologic.

  "Interchangeability" of a biosimilar means the product should:[10]
  - Provide the same clinical result as the reference innovator biologic product in any given patient.
  - Demonstrate that more than one administration to an individual has no additional safety risk or diminished efficacy when alternating or switching between the biosimilar and the reference innovator biologic.

- Gaining the P & T Committee's consensus in confirming a reasonable level of confidence that the biosimilar will:
  - Perform similarly and provide similar outcomes to that of the innovator product. This is based on the available data which may include clinical and non-clinical trials, including pharmacokinetic or pharmacodynamics studies, non-traditional clinical trial designs and which measure surrogate endpoints (e.g. white blood cell increase) rather than true health outcomes (e.g. decreased incidence of infections or hospitalization), and real world/ pharmacovigilance data.

PERSPECTIVES ON BIOSIMILARS *(Continued)*

  - Carry no additional immunogenicity risks relative to the innovator product. Biologics are comprised of proteins that can have a potential to cause an immune reaction. This is known as immunogenicity. The impact of immunogenicity depends on the extent to which the body reacts to the protein and the development of both neutralizing and non-neutralizing antibodies that can limit the Biologic's (or biosimilar's) efficacy or affect its adverse event profile. Any differences, including manufacturing variances, must be shown not to increase immunogenicity risks. Post-marketing safety monitoring should be tracked. This is because rare, but potentially serious safety risks may not be detected during pre-approval clinical testing, because the size of the population exposed may not be large enough to assess rare events.

- Determining how the biosimilar should be covered in circumstances when the biosimilar may not receive FDA approval for all indications of the reference product.
- Considering utilization management strategies (e.g. prior authorization, step therapy, quantity limits) in a manner that assures appropriate use and steers toward selected preferred product(s), (the biosimilar, reference product and/or other products options in the class), which will provide the best value and positive net health outcomes.

Other Issues for Consideration

Other issues yet to be resolved for biosimilars are the interchangeability and standardized naming conventions of biosimilars:

- Interchangeability

  The FDA has yet to decide how pharmaceutical manufacturers will prove that biosimilars are interchangeable with its reference product and safely be changed (substituted) by a pharmacist. Although FDA guidance on biosimilars,[10] includes interchangeability, it is still uncertain about the appropriate data and clinical trial designs that manufacturers will need to provide as proof of interchangeability. Payers need to be vigilant in updating health plan contracts, as further guidance on interchangeability and pharmacist substitution law is clarified. Additionally, payers need to monitor individual state laws that may supersede federal law and restrict the substitution of "interchangeable" biosimilars.

- Biosimilar Naming Conventions

  The naming convention for biosimilars continues to be debated. Currently all medications are named with an International Nonproprietary Name (INN) that identifies the pharmaceutical substance(s) or active pharmaceutical ingredient in the medication. The INN is globally recognized and considered public property. This naming system has been administered by the World Health Organization (WHO) since 1953 and has been used to identify the active pharmaceutical ingredient in all medicines.[9]

  Originator manufacturers are advocating that a modified INN for biosimilars be used (e.g. addition of a prefix or suffix to that would differentiate the product from the innovator). In contrast, biosimilar manufacturers are advocating that their products carry the same INN as the reference products and indicate that using a modified INN would impede their ability to compete fairly in the marketplace, create confusion, and potentially limit patient access to their medication.

The approval of the first biosimilar product has taken us one step closer in providing clarity on the approval pathway for biosimilars and the future impact that these products will have on market competition, reducing cost, and improving patient access to medications and overall quality care.

References:

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3. Medical Marketing & Media. FDA panel to weigh first biosimilar application. January 5, 2015. http://www.mmm-online.com/fda-panel-to-weigh-first-biosimilar-application/article/390976/. Accessed 1/13/2015.
4. Neulasta® (pegfilgrastim) prescribing information, Amgen. V15 December 2014.
5. Neupogen® (filgrastim) prescribing information, Amgen. V23, 2013.
6. Granix (tbo-filgrastim) prescribing information, Teva. December 2014.
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9. World Health Organization. Guidance on International Nonpropietary Names (INN). http://www.who.int/medicines/services/inn/innquidance/en/. Accessed January 14, 2015.
10. FDA website. Biosimilars. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/default.htm. Accessed January 14, 2015.

1-6 are missing, 9 and 10 appear to be out of order

HPMS OMS UPDATE

In CMS's March 6, 2015 memo, CMS announced recent updates regarding the use of the Medicare Part D Overutilization Monitoring System (OMS). The updates are as follows:

- Based on input from the Centers for Disease Control and Prevention (CDC), combination products containing buprenorphine and naloxone (e.g. Bunavail™, Suboxone®, and Zubsolv®) will be removed from the opioid list effective April 2015. These products are being removed because they are indicated for treatment of opioid dependence and the recommended daily target dose exceeds the OMS opioid threshold of 120mg morphine equivalent dose (MED). CMS recommends that Plans' drug utilization review programs be used to identify concurrent use of these products with other opioids in order to address inappropriate use.
- Currently, Plans submit response codes to OMS to describe beneficiary-specific POS edits implemented based on case management of the beneficiary's potential overutilization of opioids. The PS1 and PS2 Response Codes are applied only after CMS receives the beneficiary-specific POS edit notice from the Plan through MARx. (The PS1 code correspond to when no drugs in the therapeutic class are approved and the PS2 code correspond to when selected drugs in the therapeutic class are approved.) Effective April 2015, the known exception logic for these codes is based on the actual implementation date, rather than the notification date, submitted in MARx for the POS edit. This change is necessary because a proposed POS edit described in the beneficiary notice may be reversed; e.g. due to a coverage determination or appeal.
- A new Part D Overutilization mailbox (PartD_OM@cms.hhs.gov) has been established. Plans are to use the mailbox in submitting questions or suggestions related to overutilization management, the OMS, or POS edit information in MARx to CMS. It should also be used in sending copies of non-opioid, beneficiary-specific POS edit notices.

The changes above will be included in the updated Overutilization Monitoring System User Guide on the Patient Safety Analysis Website.

2015 PART C & D CALL CENTER MONITORING AND GUIDANCE

On March 2, 2015 HPMS released a memo entitled "2015 Part C and Part D Call Center Monitoring and Guidance for Timeliness and Accessibility Studies". This guidance applies to all Medicare Advantage Organizations, Prescription Drug Plan Sponsors and Medicare/ Medicaid Plans.

Plan Sponsors must verify the accuracy of their CY2015 Medicare Part D call center phone numbers in the Health Plan Management System (HPMS). CMS is requesting Plan Sponsors conduct a review and update (as appropriate) the following information in HPMS:

- Current and prospective enrollee toll-free beneficiary call center phone numbers
- Toll-free pharmacy help desk numbers
- Current and prospective enrollee toll-free TTY numbers

CMS continues to monitor Part C and Part D call centers for CY2015. The memo describes the elements and the two studies below.

Timeliness Study

This is conducted throughout the year on Medicare Part C and Part D current enrollee beneficiary call center phone lines and pharmacy technical help desk lines determining the average hold times and disconnect rates. Quarterly compliance actions are taken when a Plan Sponsor fails to maintain an average hold time of two minutes or less, and when a Plan Sponsor has an average disconnect rate greater than five percent. CMS may also take compliance actions when a Plan Sponsor is either an outlier with respect to other sponsors, or so far below CMS's acceptable expectations that compliance action is necessary. CMS will post results quarterly via the Health Plan Management System (HPMS).

CMS will issue email notices to Plan Sponsors who are non-compliant. 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. cumulative instead of quarterly results); CMS will not contemplate disputes based on Part D Sponsor's internal monitoring outcomes.

Accessibility Study

This is conducted from March through June, compliance actions will be taken by CMS when an organization's interpreter availability is less than 75 percent, or its TTY service score is lower than 60 percent. CMS will take compliance actions when a Plan Sponsor is either an outlier with respect to other sponsors, or so far below CMS's acceptable expectations that communication to the Plan Sponsor is necessary in order to verify the Plan Sponsors provides potential enrollees with the services they are permitted. These areas include, 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 a Plan Sponsors potential enrollees.

CMS will provide complete results to the Compliance Officer via a letter emailed to them for each associated contract ID. Upon Plan Sponsor's 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 TTY calls); CMS will not contemplate disputes based on Part D Sponsors internal monitoring outcomes.

CMS provided in the memo interpreter availability and TTY functionality tips to assist Plan Sponsors to better improve their results.

CMS strongly urges Plan Sponsors to review and utilize the Office of Minority Health's (OMH) National Standards on Culturally and Linguistically Appropriate Services in Health and Health Care (National CLAS Standards) and it's Blueprint. The National CLAS Standards may assist Sponsors in the implementation of culturally and linguistically applicable services.

UPCOMING CMS CONFERENCES

Upcoming CMS Conferences

CMS has scheduled upcoming conferences geared towards Medicare Advantage & Prescription Drug Plan sponsors. Below you will find details on upcoming CMS conferences.

Conference Title: *2015 Medicare Advantage & Prescription Drug Plan Spring Conference& Webcast*

When: Wednesday, May 6, 2015 from 9:30 AM – 4:30 EDT

Where: CMS Central Office, Baltimore, MD & Virtually via Simultaneous Webcast

Summary: CMS holds this conference annually and provides new information for Medicare Advantage & Prescription Drug Plan sponsoring organizations. CMS experts will present on various topics that are geared towards staff-level operations, mid-level management, and senior executives. Registration is required and there are a limited number of seats to attend in person.

Topics Include:

- 2016 Policy and Technical Changes to the Drug Benefit Program
- 2016 Call Letter Updates (Medicare Part C)
- 2016 Call Letter Updates (Medicare Part D)
- QIP CCIP
- Network Management Module
- Update and Enrollment Information Session (Panel)
- Be Proactive: Support the Fight Against Fraud, Waste and Abuse (FWA)
- Open Q & A Session

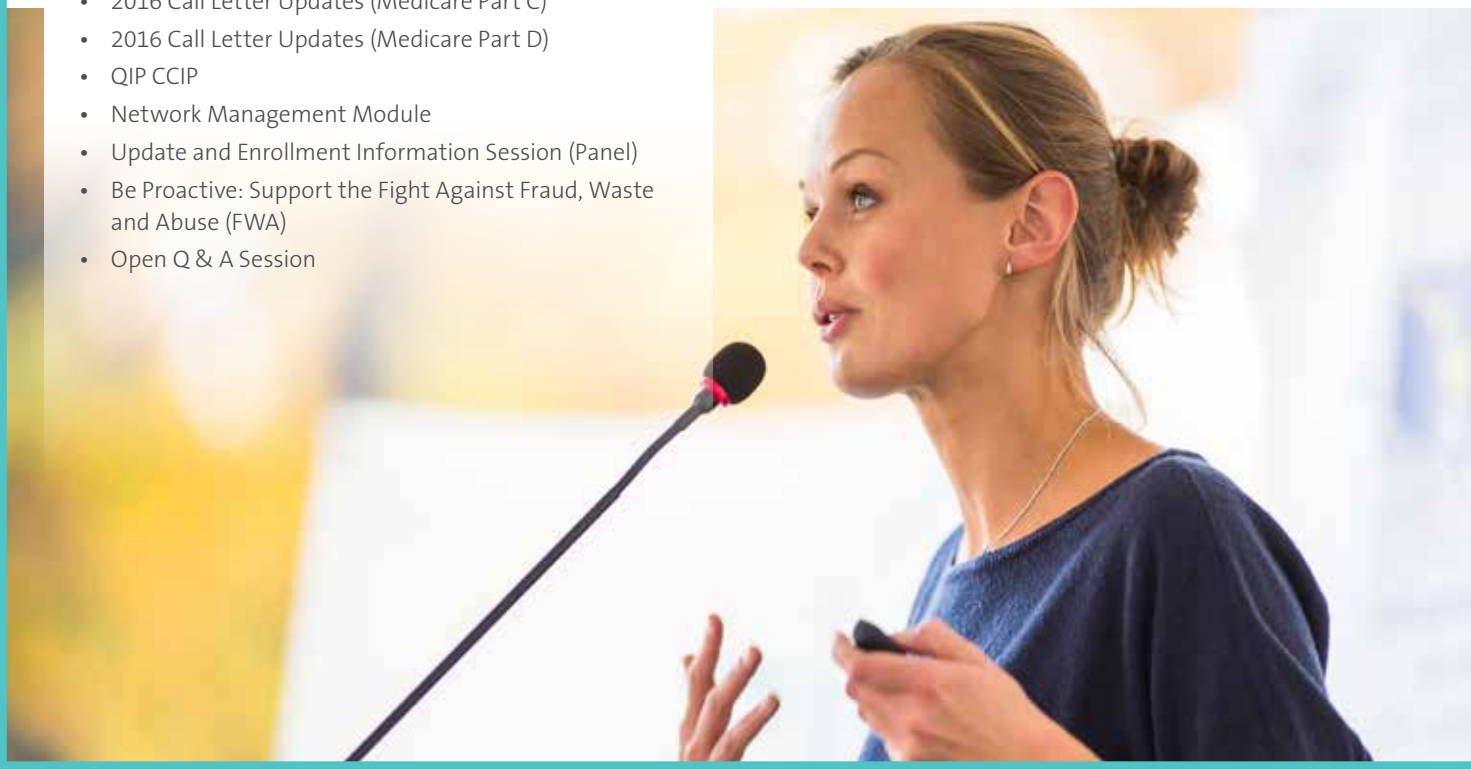
Conference Title: *CMS 2015 Medicare Advantage and Prescription Drug Plan Audit & Enforcement Conference & Webcast*

When: Tuesday, June 16, 2015, 9:30 AM – 4:30 PM EDT

Where: CMS Central Office, Baltimore, MD & Virtually via Simultaneous Webcast

Summary: CMS holds this conference annually and provides information on the topic of audit and enforcement activity for Medicare Advantage & Prescription Drug Plan sponsoring organizations. Registration is required and there are a limited number of seats to attend in person.

Topics Include: Last year CMS experts shared best practices of high performing organizations, common findings from audits, and enforcement consequences. CMS topics and agenda for 2015 are coming soon.



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CMS TIMELINE

May 8, 2015	Release of 2016 Bid Upload and Actuarial Certification module in HPMS
May 8, 2015	Release of 2016 Formulary Submission Module in HPMS
May 29, 2015	Release of the 2016 Marketing Module in HPMS to begin submitting 2016 marketing materials
June 5, 2015	Deadline for submission of CY 2016 Supplemental Formulary files and Additional Demonstration Drug (ADD) file (Medicare-Medicaid Plans Only)
June 16, 2015	MA & PDP Audit & Enforcement Conference and Webcast

About our Authors

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
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