Health Care Communiqué

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Best Practices for Part C and D Plan Reported Data Validation

Solid Benefit Guidance
ARTHUR J. GALLAGHER & CO.

Teresa Cunningham, Compliance Manager

CMS has been focusing on Data Validation Training Best Practices for Part D and C Reviewers.

CMS released an HPMS Memo titled "Best Practices for Part C and D Plan Reported Data Validation" on March 31, 2016. This memo included information regarding data validation which will take place from April 1, 2016 – June 30, 2016 and will incorporate all 2015 data submitted to CMS by March 31, 2016. The data validation reviewer must submit findings from the annual data validation review to CMS by June 30, 2016.

Annually, each Part C and D sponsor is expected to go through an annual validation of the data they provided as part of their Part C and D Reporting Requirements from CY2015. Each Part D Sponsor is required to select a data validation reviewer (contractor) to conduct the audit.

On February 25, 2016 CMS released an HPMS Memo titled "2016 Data Validation Training for Contractors" which announced the availability of the 2016 data validation training. CMS would like to ensure the reviewers are informed of the best practices noted below, so they can make use of and encourage effective and dependable data validation reviewers.

- The reviewer must remain objective, an independent third party and avoid functioning in a consulting capacity

Consultants who offer management consulting (i.e. mock audits, pre-assessments or any other type of review on reported data) or support the sponsoring organization with their reporting procedures, process or data systems used in storing, collecting, or reporting the Part C and D Reporting Requirements data to CMS may not perform the data validation review for that sponsor.

- The data validation reviewer's emphasis should be to determine, after a thorough evaluation, if sponsors' systems, programs, data, etc. are correct, dependable, acceptable, and complete based on instructions and standards outlined in the Data Validation Procedure Manual and CMS' policies.

  Deficiencies in a sponsor's policies and procedures, or general non-compliance with CMS' Part C and D policies, may consequently cause their reported data to be incorrect or partial.

- The data validation reviewer should remain unbiased. For example, he/she should not pass views on the perceived value of sponsors' systems, programs, data, etc. or develop findings based on personal indifferences or any other method not addressed in the outlined standards or CMS' policies and procedures.

- The data validation reviewer should provide universal feedback and detailed information on deficiencies to help sponsors improve. On the other hand, corrective action plans submitted to CMS by sponsors (either written or verbal) are not needed to be provided to the reviewer.

- The data validation reviewer should maintain privacy of sponsors' confidential information. The reviewer should avoid sharing general or specific information about how sponsors' data look and/or compare to one another. To encourage successful communication, open dialogues of any issues and findings with the specific sponsor are encouraged. The reviewer should refrain from discussing a specific sponsor's issues and findings with other sponsors. As described in the Data Validation Procedure Manual, a sponsor has the right to appeal any Not Pass determination(s) it receives for the Part C and/or Part D reporting sections or for the overall combined Part C and Part D determination.

The data validation reviewer functions as a key function to strengthen the accuracy and comparability of plan reported data.

CMS plans to continue to work with sponsors and data validation reviewers to enhance the data validation standards and training required to make sure there is a uniform level of functionality with all data validation contractors.

This summer CMS will solicit feedback through the Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) process on proposed CY2017 Part C and D Reporting Requirements along with the CY2017 Part C and D Data Validation materials.

CMS Part D Prescriber Enrollment Requirements- Delay in Enforcement

Sandy Om, Area Vice President

CMS announced that they are delaying enforcement of the Part D Prescriber Enrollment Requirements until February 1, 2017. This update was communicated in an HPMS Memo released on March 1, 2016.

CMS decided to delay implementation because they wanted to ensure that they could enforce this in a way that would minimize the potential for disrupting beneficiaries' access to needed Part D medications.

CMS feels that with the delay in the roll out of this new requirement, prescribers should have sufficient time to complete their enrollment into Medicare. CMS also feels that this delay will assist Part D Sponsors and their pharmacy benefit managers (PBMs) as well as Medicare Advantage Organizations (MAOs) offering MA-PDs additional time needed to make system enhancements necessary to comply with the Part D Prescriber Enrollment Requirement and various guidance documents released by CMS since publication of the IFC, in particular the comprehensive Technical Guidance released on December 29, 2015.

CMS strongly encourages MAOs and Part D Sponsors to continue prescriber outreach activities. This should include both outreach and monitoring or prescriber enrollment trends and potential beneficiary impact. These continued efforts will help CMS to continue to evaluate implementation of the prescriber enrollment requirement.

In addition, CMS is also strongly encouraging prescribers of Part D drugs (except those who meet the definition of "other authorized prescribers") to submit Medicare enrollment applications or opt-out affidavits to their Medicare Administrative Contractors (MACs) before August 1, 2016. This will ensure that MACs have sufficient time to process the prescribers' applications or opt out affidavits and will prevent prescription drug claims associated with their prescriptions from being rejected by Part D plans beginning February 1, 2017. Prescribers can refer to the following CMS website for more information: go.cms.gov/PrescriberEnrollment.

What should plans be doing?

- Review the HPMS Memo titled "Medicare D Prescriber Enrollment Technical Guidance" in detail.
- Monitor reports on prescribers who have not yet enrolled or opted out.
- Communicate with prescribers who have not yet enrolled or opted out.
- Review volume of claims rejects that would occur when this goes into place.
- Ensure that the systems will be ready to adjudicate these claims appropriately.
- Confirm member and prescriber communications will be implemented timely.
- Make sure that customer service representatives are trained in this new requirement so they are able to address beneficiary questions.

The Prescriber Enrollment process will allow CMS to validate a prescriber's credentials and will prevent unqualified physicians from prescribing Part D drugs. In addition, if a physician/practitioner (including dentists) decides to opt out of Medicare, they will not be eligible to receive reimbursement for items and services covered by traditional Medicare or a Medicare Advantage plan, including those covered as supplemental benefits, except for emergency and urgent care services as permitted by regulations.

Part D sponsors should continue to actively monitor the progress of enrolled prescribers to minimize negative impact to their enrollees.

Part D Enhanced Medication Therapy Management Model

Treesie Farmer CFE, CHC, Director of Compliance

On March 16, 2016 via HPMS, CMS announced the release of the Medication Therapy Management (MTM) pilot audit protocol for the 2016 calendar year and provided an update on the Provider Network Accuracy (PNA) pilot.

The MTM pilot audit protocol is similar to the audit process documents for existing program audit areas. The MTM pilot protocol defines the audit purpose, universe and sample selection processes, the evidence required for review and submission, and the compliance standards that will be tested during the audit.

CMS will conduct the MTM program audit via webinar during week two of the CY 2016 program audits and will be subject to the pre-audit activities described in Attachment X-Audit Process Document included with the pilot protocol. The results of the pilot will be displayed in the draft audit report, but the results of

the MTM pilot will not count against a sponsor and will not factor into the overall audit score. Therefore, the results of the MTM pilot will not appear in the final audit report. The results of the pilot will be displayed in the draft audit report, but the results of the MTM pilot will not count against a sponsor and will no factor into the overall audit score. Therefore, the results of the MTM pilot will not appear in the final audit report. Any sponsors with an MTM program that are scheduled for a CY 2016 audit after the release of the MTM pilot protocol may be included in the MTM pilot. However, CMS will not retrospectively apply the pilot protocol to sponsors audited prior to the MTM protocol release.

CMS also provided an update on the status of the Provider Network Accuracy pilot they are developing. CMS stated this pilot will test the accuracy of the data in a sponsor's provider directory as well as in their Health Service Delivery (HSD) tables, but will not evaluate the adequacy of a sponsor's network. CMS also stated they are currently engaged in wide scale monitoring efforts with respect to network accuracy and provider directories. The Medicare Parts C & D Oversight and Enforcement Group (MOEG), in coordination with the Medicare Drug & Health Plan Contract Administration Group (MCAG) are performing detailed monitoring, auditing and validation.

MCAG will be selecting a number of contracts and calling providers in those contract's provider directories to ensure that the provider is still contracted with the plan and that other information about the provider is correct. When errors are identified, MCAG will notify sponsors of any errors identified in their directories with instructions to correct the errors. MOEG will wait for a minimum of 30 days after a sponsor has been notified of their errors and then validate that a sponsor's provider directory and corresponding HSD tables have been updated and reflect accurate information. MOEG will notify sponsors who continue to have errors in their directories or HSD tables via a letter.

The PNA pilot will not be administered as a normal audit protocol and will not be performed in conjunction with the CY 2016 program audits. The results will also not appear in an audit report. However, CMS reminded plans that organizations who fail to correct and come into compliance with requirements may be subject to possible enforcement action, including civil money penalties or enrollment sanctions.

Biosimilars - FDA approves Biosimilar for Remicade®

Lynn Nishida, Area Vice President, Pharmacy

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Inflectra™ is the second biosimilar approved by the FDA, after Sandoz's filgrastim-sndz, Zarxio®, approved in early 2015 as a biosimilar of Amgen's Neupogen® (filgrastim) for the treatment of low white blood cells (neutropenia).

On April 5, 2016, the FDA approved Celltrion's infliximab-dybb (Inflectra™) as a biosimilar to Janssen's Remicade® (reference product). Celltrion will partner with Pfizer to market Inflectra™ in the U.S.

Products like Inflectra™ and Zarxio® are known as biosimilars, not generics, because they are similar, but not exact copies of their original reference products, Remicade® and Neupogen®.

To distinguish a biosimilar from its reference product, the naming convention for biosimilars uses the reference biologic's nonproprietary name, followed by a suffix that is used to identify the manufacturer of a particular biosimilar:

Biosimilar	Nonproprietary Name – Manufacturer Suffix
Inflectra™	infliximab-dybb
Zarxio®	filgrastim-sndz

Inflectra™ was clinically studied in rheumatoid arthritis and ankylosing spondylitis (two of the six conditions that it is approved for). Pharmacologic data on the functional and structural characteristics, safety, and immunogenicity for Inflectra™ was also provided to the FDA.

Based on the overall data (clinical studies and pharmacologic data), the FDA decided that the evidence supported Inflectra™'s biosimilarity to Remicade® for the indications that were approved. FDA was willing to forego the requirement of clinical studies of a biosimilar for each and every indication that it is approved for.

Inflectra™ is not an "interchangeable" biosimilar. To date, the FDA has yet to approve a biosimilar with an "interchangeable" designation, which would allow pharmacists (except where state law prohibits) to automatically substitute a biosimilar for its reference product.

With the exception of the product name, manufacturer, indications, and a statement on Inflectra™'s biosimilarity to Remicade®, Inflectra™'s package insert is the same as Remicade®'s, according to the following document: http://www.remicade.com/shared/product/remicade/prescribing-information.pdf

Financial Impact and Projections

The introduction of Inflectra™ is anticipated to bring the benefits of favorable market competition among high cost specialty biologics for payers. Because Inflectra™ is administered as an intravenous infusion, the majority of its utilization and cost impact will be on the medical benefit for payers.

Inflectra™ is expected to be about 20% - 30% less expensive than Remicade®. Annual medication cost for one patient on Remicade® can range from ~ $26,000, up to $ 52,000. Cost is largely dependent on the frequency of administration (e.g., every 4 – 8 weeks) and dosing that will vary with the patient's weight, specific condition being treated and severity of disease.

At a lower price, Inflectra™ will be a prime competitor of Remicade®, which reached approximately $4.5 billion in annual market sales in 2015.

Biosimilars for infliximab are approved in 71 other counties worldwide. And Remsima™ is Celltrion's biosimilar for Remicade®, which was approved by the European Medicines Agency (EMA) in February 2015 and marketed in Europe).

If Inflectra™ performs in the U.S. market as well as Celltrion's European biosimilar, Remsima™ did in 2015, market sales of Remicade® could see as much as a 20% decline. A decline of this magnitude could translate to ~ $225 million in annual savings nationwide.

Pfizer is not anticipating to launch Inflectra™ until June 29, 2016. Court litigation and patent appeal rulings could delay Pfizer's launch by 180 days past Inflectra™'s FDA approval date (until October 2, 2016) or longer.

SBG Perspective:

- Biosimilars have the potential to stimulate favorable market competition to drive lower prices, provide cost savings, and improve the quality of biologic products.
- The recent approval of Inflectra™ provides yet another substantial opportunity for payers to evolve their strategies to manage high cost biologic, specialty medications.

SBG Recommends:

- Timely clinical review of Inflectra™ by the Payer's delegated Pharmacy and Therapeutics Committee, (or applicable Review Committee) to evaluate how to best position and cover Inflectra™, relative to other immune biologic options used for similar indications.
- Physician outreach and education about Inflectra™ to encourage the acceptance and adoption of biosimilars as viable and cost-effective treatment options.
- Implementation of appropriate medication coverage criteria for Inflectra™, as well as alignment of all other immune biologic medication coverage policies to reflect the payer's P and T Committee's determinations and positioning of these medications in a manner that will maximize their appropriate, safe, and most cost-effective use.
- For Payers, who have medication rebates handled through a third-party entity, such as a medical carrier or Pharmacy Benefits Manager (PBM): become knowledgeable and informed about existing contractual arrangements with these entities. The degree of potential savings that a payer sees from biosimilars will depend on the structure of these arrangements.
- For Payers with Medicare (Part B and D) and Medicaid lines of business: ensure that provider/vendor agreements, benefit contracts, and applicable reimbursement policies and procedures align with CMS guidance on biosimilars for appropriate reimbursement and formulary processes. This includes any necessary medical claims system enhancements needed to capture and populate additional information, codes (HCPCS codes, modifiers and NDC) for appropriate billing, tracking, and reporting of biosimilars.
- CMS issued several guidance documents to address the handling of biosimilar products for purposes of reimbursement and rebates under Medicare (Part B and D) and the Medicaid Rebate Program, including: CMS Final Rule, Part B Drugs/ Payment for Biosimilar Biological Products; https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-10-30-2.html.
- Because the majority of Inflectra™ utilization will fall under Medicare Part B, Payers should be aware that as the first marketed biosimilar, Inflectra™ will eventually receive a unique HCPCS code (a code used for medical claims billing), different from Remicade®, and paid at its own Average Sale Price (ASP) plus 6% of the reference product's ASP.
- For Commercial and Exchange lines of business, ensure benefit contracts allow for the preferential coverage of biosimilars and reimbursement terms, as appropriate.

CMS TIMELINE

June 1, 2016	Release of the 2015 DIR Submission Module in HPMS
June 6, 2016	Deadline for submission of CY 2017 bids (including Service Area Verification) for all MA plans, MA-PD plans, PDP, cost-based plans offering a Part D benefit, Medicare-Medicaid Plans (MMPs), "800 series" EGWP and direct contract EGWP applicants and renewing organizations; deadline for cost-based plans wishing to appear in the 2017 Medicare Plan Finder to submit PBPs (11:59 p.m. PDT)
Early June to Early September, 2016	CMS completes review and approval of 2017 bid data. Plans/Part D sponsors submit attestations, contracts, initial actuarial certifications, and final actuarial certifications
June 7-10, 2016	Window for submitting first round of crosswalk exception requests through HPMS
June 10, 2016	Deadline for submission of CY 2017 Supplemental Formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, Home Infusion file, and Non-Extended Day Supply file through HPMS (11:59 a.m. EDT)
June 16, 2016	2016 MA and PDP Audit and Enforcement Conference and Webcast

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About our Authors

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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:

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- PBM Auditing
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