Life & Health

Health Care Communiqué

Q1 2014

2014 PART C AND D CALL CENTER MONITORING PROTOCOLS

CMS will continue to monitor Part C and Part D Plan Sponsor call centers in 2014. CMS has contracted with IMPAQ International, LLC to monitor call centers and ensure compliance with CMS standards. CMS will be conducting two call center studies in 2014.

The first call center study will look at timeliness; it will look at current enrollee beneficiary call center phone lines to determine average hold times (time on hold after IVR before reaching a live person) and disconnect rates (unexpected dropped calls while navigating IVR or after divided by number of calls made to that phone line). This study will be conducted throughout the entire year, with quarterly compliance actions being taken for Plans that fail to maintain an average hold time of less than 2 minutes and a disconnect rate greater than 5%.

CMS may take additional compliance actions for Plans that are outliers or below CMS expectations. Examples would be for inappropriate call center closures and/or failure to maintain a toll-free telephone number for Plan members to call. Quarterly results will be found via HPMS in the Quality Performance section. Plans that are considered non-compliant will receive email notifications. Plans can challenge these findings but must use CMS data, and not their internal call monitoring results.

(continued...)

2014 PART C AND D CALL CENTER MONITORING PROTOCOLS *(Continued)*

The second call center study will look at Accuracy and Accessibility by looking at the enrollee benefit call center phone lines to determine the availability of interpreters, TTY functionality and accuracy of plan information provided by the representative in all languages. This study will be conducted between February and May, and compliance actions will occur when a Plans interpreter availability is less than 75%, its TTY service level is less than 60% and/or its rate of accuracy is less than 75%.

Results of this study will be sent via email to the Compliance Officer for each contract ID. Plans can challenge but must use CMS data and not their own internal call monitoring results.

CMS has given the following tips to help Plans be more successful:

- Review all call center telephone numbers in HPMS, on Plan website and in written material for accuracy.
- Use interpretative service personnel that are familiar with health team and Medicare benefit concepts.
- Train CSR reps to connect appropriately and stay on the line until the interpreter joins the call.
- Make sure that if the beneficiary does not select via the IVR that a live CSR joins to give them live menu options.
- Note the beneficiary's call center record with their preferred language, and track this information.
- Monitor CSR foreign language calls for accuracy.
- Train CSR to be aware of the CMS study.
- Ensure interpreters are available within 7 minutes of the caller reaching a CSR.
- Regularly test your TTY device to ensure it is working properly.
- Make sure the caller is speaking with a live person and not leaving a message for TTY beneficiaries.
- Ensure relay operators are available within 7 minutes
- Ensure that CSRs can respond to questions regarding Medicare Marketing guidelines, section 80.[1]
- Confirm that CSRs are trained on the 2014 edition of Medicare & You.
- Make sure CSRs have easy access to specific plan benefits and formulary.

REVISED PART D NOTICE OF DENIAL OF MEDICARE PRESCRIPTION DRUG COVERAGE

Beginning no later than March 1, 2014, Part D plan sponsors must use the revised, OMB-approved standardized Notice of Denial of Medicare Prescription Drug Coverage (CMS-10146).

The revised Part D standardized denial notice must be provided to Part D enrollees when a Part D plan sponsor issues a full or partial coverage determination denial.

The new notice includes instructions for inserting denial rationale language (as applicable) regarding Part D versus Part B coverage. Particularly, if a request is denied under Part D but could be covered under Part B, the plan should include an explanation of potential Part B coverage as part of the denial rationale. Additionally, if a plan (MA-PD) can approve coverage for the drug under Part B, the plan must include this information as part of the explanation of why the drug request is not covered under Part D.

REVISED OVERUTILIZATION ATTESTATION REQUIRED

In an ongoing effort to further curtail the overutilization of opioids, CMS is asking plans to revise their process for opioid management. Preliminary data analyzed as part of the Overutilization Monitoring System (OMS) has indicated that a small percentage of beneficiaries are changing Part D plans after they receive a written notice that a plan intends to implement a beneficiary-level point of service (POS) opioid claim edit. About half of these beneficiaries are switching before the required thirty (30) days for the advance written notice has passed.

The previous attestation, plans submitted, may be too restrictive for cases involving enrollees who change plans before a POS opioid claim edit has been implemented by the plan in its claims system, i.e., during the 30 days advance written notice period. Attestation was also limited to sharing of information about enrollees for whom a claim edit had been implemented and did not require plans to transfer records and actions in cases where the plan had sent an advance written notice of the pending claim edit to the enrollee, but the edit had not yet been activated in the claims system. Since the advance notice time period had not passed, this attestation potentially restricted transfer of information to enrollees for whom an opioid claim edit had been activated.

Plans were required to complete a revised attestation in HPMS by January 6, 2014. The revised attestation states that the plan requests information pertaining to the plan's Part D enrollees from former plans regarding enrollee POS opioid claim edits (regardless of status) on an ongoing basis for use in the plan's care management and fraud and abuse activities. Thus, the revised attestation is not restricted to information about enrollees with an activated opioid claim edit, but also addresses sharing of information on enrollees for which the plan has sent an advance written notice about its decision to implement such an edit.

The transfer of opioid overutilization records between plans can take weeks. As a result of this delay, CMS is strongly advising all plans to develop a process whereby they are capable of monitoring new enrollees for potential opioid overutilization in order to proactively make a request to previous plans for records and any applicable actions taken. CMS is expecting plans to honor requests for opioid information within two weeks from request.

Plans are able to view other sponsors' contact information through the HPMS home page, as well as on the CMS website, "Improving Drug Utilization Review Controls in Part D".

SBG highly recommends that you work with your PBM to ensure that you are receiving all necessary POS edits and written notification information, in a usable format, to be shared with plans requesting information for new members as well as to ensure there is a process established with PBM to implement edits for new enrollees into your plan with current POS edits.

Hydrocodone bitartrate (Zohydro™ ER) – Zogenix

SBG Perspectives - December 2013

ISSUE:

On December 17, 2013, the Centers for Medicare and Medicaid Services (CMS) issued a memorandum to all Medicare Part D Plan Sponsors encouraging the use of utilization management on a newly approved long-acting hydrocodone medication product, Zohydro™ ER.[1]

BACKGROUND:

- On October 25, 2013, the Federal Food and Drug Administration (FDA) approved Zohydro™ ER as the first single-ingredient hydrocodone product for treatment of moderate to severe chronic pain. The approval surprised many health care practitioners, since an earlier FDA advisory panel voted overwhelmingly against the product, citing concerns of its significant abuse potential and lack of a tamper-deterrent technology.[2]

  As a single ingredient opioid product, Zohydro™ ER was designed to give providers:

  – An additional option in converting patients using immediate-release hydrocodone to an extended-release alternative.

  – An alternative to other long-acting opioids such as methadone, oxycodone, and morphine.

  Zohydro™ ER is available in capsule strengths 10mg, 15mg, 20mg, 30mg, 40mg, 50mg and thus much more potent than available short-acting hydrocodone combination products that contain 5 – 7.5mg hydrocodone per pill (such as Vicodin®, Lorcet®, Vicoprofen®). Combination hydrocodone products containing acetaminophen or ibuprofen were designed to make the medication more difficult to abuse. However, this is highly disputed due to the degree of abuse and diversion observed with combination hydrocodone products.
- Greater than 131 million prescriptions for products containing hydrocodone are dispensed annually, making it the most prescribed medication in the country.
- The Drug Enforcement Association (DEA) reports that hydrocodone combination products are of the most-abused medicines in the U.S., along with oxycodone (e.g. OxyContin®).[3]

CLINICAL TRIALS SUMMARY

- Zohydro™ ER was granted FDA approval, based on a 12- week randomized, double blind, and placebo controlled trial in 302 opioid-experienced patients with moderate to severe low back pain.
  – Efficacy of greater pain relief than placebo was demonstrated based on the change in weekly pain intensity using a Numeric Rating Scale (0.48 +/- 1.56 from baseline to day 85 with Zohydro™ ER compared with 0.96 +/- 1.55 for placebo, p = 0.008).[3]
  – Patients were titrated every 3-7 days, for inadequate pain control until stabilized, or maximum dosage of 100mg every 12 hours.
  – Most commonly reported adverse events (greater than or equal to 2%) were constipation, nausea, somnolence, fatigue, headache, dizziness, dry mouth, vomiting and pruritus.

ABUSE/DIVERSION POTENTIAL:

- As a long-acting opioid, with no tamper-deterrent technology, Zohydro™ ER carries significant risk of abuse and diversion.
- The DEA classifies Zohydro™ ER as a Schedule II drug product and thus carries more strict prescription and dispensing rules as compared to available Schedule III hydrocodone combination products.
- A comprehensive Risk Evaluation and Mitigation Strategy (REMS) is in place, which:
  – Is consistent with current FDA and industry-wide guidelines for extended-release opioid products.
  – Is intended to control inappropriate prescribing, misuse and abuse of extended-release opioids while maintaining patient access to essential pain medications.
  – Requires provision of a patient-education brochure, education program for prescribers, and a tool kit for providers before dispensing.

SBG Perspectives on Zohydro™ ER

- Hydrocodone, (the main drug component in Zohydro™ ER), has an established track record for use as an effective opioid analgesic option for treatment of moderate to severe pain. However, Zohydro™ ER lacks a track record, as well as a tamper-deterrent formulation. This poses risk for abuse and diversion.
- In concert with this perspective, SBG recommends applying formulary and utilization management strategies for Zohydro™ ER to prevent misuse/overuse and the potential for diversion in a manner consistent with management of other long-acting CII opioids. This includes:

  Formulary status and/or prior authorization that is consistent with prescribing literature, and clinical evidence which encourages use of other formulary, short-acting opioid medications (e.g. generics), unless not effective in controlling moderate to severe chronic pain, or not tolerated.

  Coverage criteria that assures:

  - Clear and objective treatment goals and plan, with at least one annual medical office visit and assessment necessary for continued coverage.
  - Initiation of patients who are NOT opioid tolerant to lower dosing of Zohydro™ ER (e.g. 10mg every 12 hours), with higher strengths reserved for opioid-experienced patients.[4]
  - Discontinuation of all other around the clock opioids when Zohydro™ ER is initiated.
  - Quantity limit to prevent dispensing that exceeds dosing allowed in clinical trials (e.g. 100 mg every 12 hour). [4]

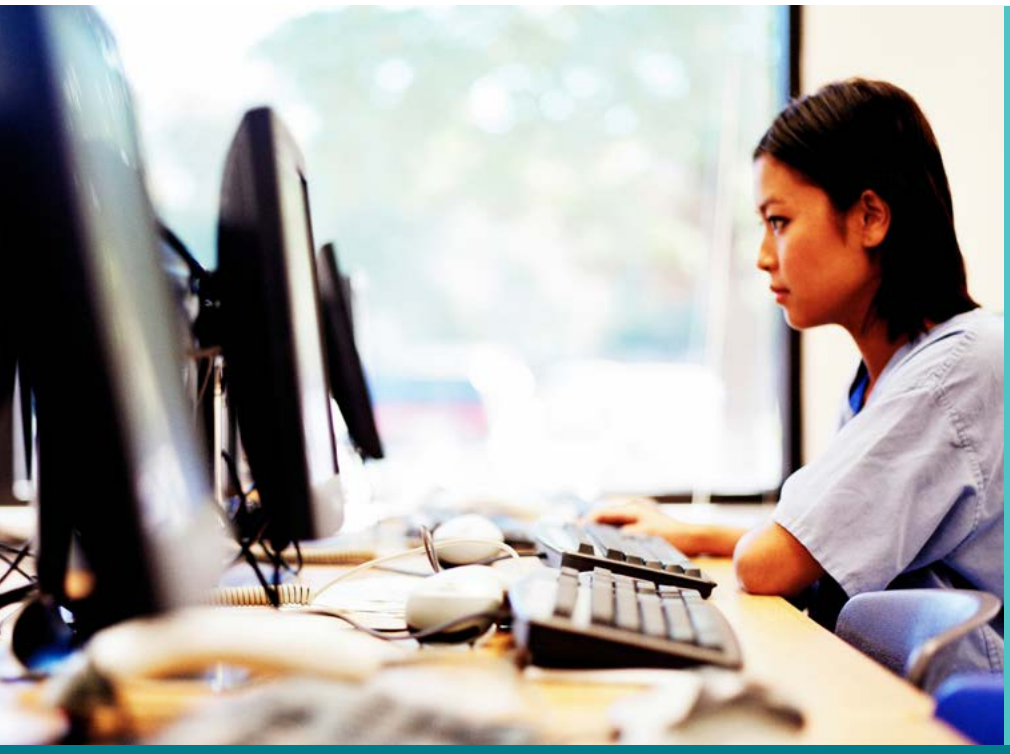
  Addition of Zohydro™ ER to retrospective DUR programs in place that identify outlier use of opioid and controlled substances.

- CMS requires Part D Sponsors to screen and review for inappropriate or excessive utilization patterns of opioids, based on cumulative morphine equivalent dose (MED) for opioids received by patients over 90 consecutive days that triggers outreach or review.
- SBG recommends an MED of 1.0 of Zohydro™ ER, which aligns with published MED for short acting-hydrocodone combination products, 5 and CMS response to SBG inquiry regarding MED to use.

Note: Prescribing literature for Zohydro™ ER provides Conversion Factors that direct the conversion of listed oral opioid analgesics (hydrocodone, oxycodone, methadone, oxymorphone, hydromorphone, morphine, codeine) to initiate Zohydro™ ER. This is NOT a table of equianalgesic doses, but should be followed closely as a guide for starting patients on Zohydro™ ER. [4]

References:

1. M. Majestic. Centers for Medicare and Medicaid Services. Center for Program Integrity. Letter Dec 17, 2013; Alert – Zohydro™ ER.
2. FDA Panel Gives Thumbs Down to Opioid. Med Page Today. December 7, 2012. http://www.medpagetoday.com/PainManagement/PainManagement/36334. Accessed December 19, 2013.
3. Drug Enforcement Agency. HYPERLINK "http://www.dea.gov/" www.DEA.gov. Accessed December 19, 2013.
4. Zohydro™ ER (package insert). San Diego, CA: Zogenix; October 2013.
5. Ref: Von Korff M etal. Defacto Long-term Opioid therapy for Non-cancer Pain. Clinical Journal of Pain. July/August 2008 – Volume 24(6): 521-27.



CMS Calendar

February 1	Coordination of Benefits Contractor (COBC) formally becomes Benefits Coordinator and Recovery Center (BCRC)
February 3-14	CY 2015 Plan Benefit Package/Summary of Benefits Beta Testing
February 25	CY 2015 Applications Due
March 7	2015 Call Letter Comments Due

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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:

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