NCPA Summary of CMS 2013 Part D Final Rule
Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes

Coverage Gap Discount Program – Pharmacy Prompt Payment
- Part D sponsors must reimburse a pharmacy, including long-term care pharmacies and home infusion pharmacies, the amount of the applicable coverage gap discount no later than 14 days after the date of dispensing, if the claim is submitted electronically, and no later than 30 days after the date of dispensing, if the claim is submitted otherwise.
- CMS clarifies that the date of dispensing for purposes of long-term care and home infusion pharmacies can be interpreted as the date the pharmacy submits the discounted claim for reimbursement and not the actual date the pharmacy dispensed the medication.

Inclusion of Benzodiazepines and Barbiturates as Part D Covered Drugs
- Beginning in 2013, Medicare Part D plans must provide coverage for benzodiazepines and barbiturates (when used for epilepsy, cancer, or a chronic mental health condition).

Pharmacy Benefit Manager’s Transparency Requirements
- CMS will implement the Affordable Care Act (“ACA”) provisions regarding PBM transparency requirements within the Part D program. Each entity that provides pharmacy benefits management services must provide to the Part D sponsor, and each Part D sponsor must provide to CMS, the following:
  1. The total number of prescriptions that were dispensed.
  2. The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies.
  3. The percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medication to the general public), that is paid by the Part D sponsor or PBM under the contract.
  4. The aggregate amount and type of rebates, discounts, or price concessions (excluding bona fide service fees as defined in §423.501) that the PBM negotiates that are attributable to patient utilization under the plan.
  5. The aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed.
  6. The aggregate amount of the difference between the amount the Part D sponsor pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies.
- CMS will not introduce a definition of PBM in this regulation, but emphasizes that the entity's function is more important than the form of its name.
- PBM transparency requirements apply to both Part D sponsors and to entities that provide PBM services to Part D sponsors.
• CMS recognizes that consistent definitions of independent, chain, supermarket, and mass merchandiser pharmacies are necessary for accurate reporting and will issue further sub regulatory guidance regarding this reporting requirement before requiring Part D sponsors to submit this information.

• CMS states there is no substantive difference between the aggregate amount of rebates, discounts, and price concessions “attributable to patient utilization” and DIR (direct and indirect remuneration) currently reported under the Part D program. CMS releases annual DIR reporting guidance.

• DIR is any and all rebates, subsidies, or other price concessions from any source (including manufacturers, pharmacies, enrollees, or any other person) that serve to decrease the costs incurred by the Part D sponsor (whether directly or indirectly) for the Part D drug.

• CMS states that even rebates, discounts, and price concessions for things such as formulary placement for a particular product, administrative services, or generic dispensing incentives are indirectly attributable to patient utilization, and are subject to the reporting requirements.

• CMS collected PBM spread amounts aggregated to the plan benefit package level in the 2010 DIR reporting requirements. CMS will add PBM spread amounts for retail pharmacies and PBM spread amounts for mail order pharmacies to the existing DIR reporting requirements.

• CMS modified the proposed definition of bona fide service fees in §423.501 by omitting the examples of bona fide services listed in the proposed definition. Bona fide services are subject to change as new ones are developed or other bona fide services are discontinued. CMS will elaborate on the definition of bona fide service fees in sub regulatory guidance, as they have done in DIR reporting guidance.

• CMS is using the following definition of bona fide service fees: fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

• If there is no difference between the amount the Part D sponsor pays the PBM and the amount that the PBM pays mail order pharmacies (that is, if Part D sponsors use pass-through pricing for their mail order pharmacies), then the amount should be reported as zero.

• Because only the aggregate amount of the difference between the amount the Part D sponsors pays the PBM and the amount the PBM pays retail pharmacies is reported, the PBM's drug acquisition costs drugs will not be disclosed.

• Sponsors may use either the lock-in pricing or pass-through pricing approach when contracting with PBMs, but they must use the price ultimately received by the pharmacy (or other dispensing provider) as the basis for calculating beneficiary cost sharing, total drug spend, and cost reporting to CMS.

• For CMS to appropriately monitor whether plans are calculating their average amount paid to a pharmacy as compared to what the plan paid the PBM, NCPA contends that plans have to report their MAC lists to CMS no less frequently than a monthly basis. CMS recognized NCPA’s request and noted this may be more appropriate as suggestions for revisions to prompt payment and pricing standard update requirements already codified at §§423.505(b)(21) and 423.520.
• Penalties for failure to provide pharmacy benefits manager data include the following: (i) Failure to provide timely information—the amount of the penalty shall be increased by $10,000 for each day in which such information has not been provided and, if such information is not reported within 90 days of the deadline, the agreement shall be suspended until the date such information is reported and (ii) False information—anyone that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information.

Independence of LTC Consultant Pharmacists
• CMS has chosen not to finalize the separation of the consultant pharmacist from the dispensing pharmacy at this time. CMS stated that a requirement for independent consultant pharmacists will not solve the entire problem, but would be disruptive for much of the LTC industry and result in higher costs to the facilities and consultant pharmacists. CMS also states that the entire industry (not just consultant pharmacists) should implement steps to curtail overutilization and inappropriate drug use in LTC facilities.
• CMS does say they may consider requiring broader changes in future notice and comment rulemaking. In the interim CMS will closely evaluate the number of deficiency citations for unnecessary drug use and will monitor the two new performance measures (based on resident assessment information reported in MDS 3.0 and available later in 2012 on http://www.medicare.gov/NHcompare/home.asp) to track the use of antipsychotics in LTC facilities. CMS will also participate in a DHHS initiative focused on the use of antipsychotics for persons with Alzheimer's disease.
• CMS is soliciting additional comments regarding a comprehensive approach to eliminate overprescribing and the use of chemical restraints in LTC.
• CMS is asking LTC industry to voluntarily adopt the following changes to increase transparency:
  o separate contracting for LTC consulting services from dispensing and other pharmacy services;
  o payment by LTC facilities of a fair market rate for consultant pharmacist services;
  o disclosure by the consultant pharmacists to the LTC facility of any affiliations that would pose potential conflicts of interest; or the execution by the consultant pharmacists of an integrity agreement.
• CMS expects LTC pharmacies to collect data on the number and type of interventions recommended by the consultant pharmacists and on the outcomes of those recommendations and work with entities such as the Pharmacy Quality Alliance (PQA) to develop performance measures to assess consultant pharmacist effectiveness.

• CMS is soliciting further comment (due 6/12/12) to better define the problem and frame a more comprehensive solution to address concerns regarding medication management and quality in LTC related to the following three issues (including specific questions):
  o Enhancing medication management and the effectiveness of medication review.
    ✓ What actions/steps should be taken to strengthen attending physician (and other prescribers) medication management and prescribing practices to ensure the best quality of care for the nursing home resident?
    ✓ What is and should be the role of nursing home medical director in overseeing the attending physician (or other prescribers) medication management activities?
What actions, if any, should the medical director take when attending physicians (or other prescribers) fail to engage in appropriate/adequate medication management activities?

What actions/steps could be undertaken to establish and ensure the independence and effectiveness of a consultant pharmacist in conducting their medication reviews on behalf of nursing home residents?

What training and best practice models would assist all nursing home staff to better understand behavior signs and symptoms and respond appropriately and effectively in assisting and caring for nursing home residents?

Data collection and use.

What data are needed to enable and support the Medicare and Medicaid programs and others in monitoring the appropriateness and adequacy of medication management activities, including the use of antipsychotics drugs?

What data are needed to enable CMS to study the effectiveness of consultant pharmacist medication reviews?

What data are needed to create public performance metrics regarding the independence of consultant pharmacists and prescribers from pharmacies and drug manufacturers/distributors?

Are data needed on the number and type of interventions recommended by consultant pharmacists and on the outcomes of those recommendations? If so, how could such data be used and by whom?

Increasing transparency.

What specific details regarding the financial (and other) arrangements between LTC facilities, consultant pharmacists, and LTC pharmacies providing consulting and/or dispensing services should be disclosed, and to whom should this information be available?

Should the public be informed of the financial and other arrangements between LTC facilities, consultant pharmacists, and LTC pharmacies providing consulting and/or dispensing services? If so, what metrics could be used?

What information is needed to assess the independence and adequacy of physician (and other prescriber) medication management and oversight on behalf of nursing home patients? What metrics could be used to assess the adequacy and appropriateness of prescriber response to consultant pharmacist recommendations?

What metrics could be used to describe the adequacy and appropriateness of a LTC facility's medication management program?

Describe the incentives and other arrangements that create the conflict of interest in LTC that contributes to overutilization and inappropriate drug use in LTC facilities. How can the conflict of interest stemming from these incentives and arrangements be contained or eliminated?

Plan Performance Ratings

- CMS may terminate an MA organization or Part D sponsor contract for a failure to achieve at least a 3-star summary plan performance rating for 3 consecutive contract years. Plan ratings issued by CMS before September 1, 2012 are not included in the calculation of the 3-year period.
- CMS believes that 3 years is sufficient time for a sponsor to develop and implement corrective action and for improved performance to be reflected in the star ratings issued at the conclusion of the 3-year period.
Clarifying Coverage of Durable Medical Equipment

- CMS will allow Medicare Advantage (MA) plans to limit DME supply coverage to certain manufacturers but the ability to limit DME brands, items, and supplies to specific manufacturers does not apply to orthotics and prosthetics.
- CMS will provide for beneficiary protections under the DME supply limitation proposal, including ensuring that patients who demonstrate a medical necessity for non-preferred brands have access to those brands, allowing for a transition period for new enrollees from non-preferred to preferred brands (at the enrollee’s request), and prohibiting MA plans from eliminating preferred coverage of a particular brand mid-year.

Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program

- CMS will delay their proposal to implement a program with a daily prorated patient cost-sharing rate for prescriptions dispensed by a network pharmacy for less than a 30 days’ supply of certain covered Part D drugs until January 1, 2014. The delay is to allow more time for Part D sponsors, PBMs, network pharmacies, and industry standard development organizations to work through the details.
- Originally the proposal would have applied to Part D drugs that are for an initial fill of a new medication; are intended to allow the enrollee to synchronize refill dates of multiple drugs, or are dispensed in accordance with short-cycle fills in long-term care facilities beginning January 1, 2013. The requirement will now apply to all drugs dispensed for less than a month's supply.
- "Daily cost-sharing rate" means (1) monthly copayment under the enrollee's Part D plan, divided by 30 or 31 and rounded to the nearest lower dollar amount, if any, or to another amount, but in no event to an amount that would require the enrollee to pay more for a month's supply of the prescription than would otherwise be the case; or (2) coinsurance percentage. CMS added the "if any" language specifically in recognition that some daily cost-sharing rates may be below $1.

- This requirement will be limited to drugs that are in the form of solid oral doses and may be dispensed for a supply less than 30 days under applicable law. In addition, this requirement will not apply to antibiotics or drugs dispensed in their original container as indicated in the FDA Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance.
- Related to dispensing fees associated with short fills, CMS is urging industry to develop appropriate coding so that pharmacies can communicate the reason for short fills, although the reason is not required. Note CMS says it is not unreasonable for sponsors to ask pharmacies to attest to the reason for a short fill.
- To the extent Part D sponsors wish to implement daily cost-sharing rates for contract year 2013, they may do so on a voluntary basis for purposes of short-cycle dispensing as an example.
- Regarding daily prorated cost sharing amounts in the LTC setting, there is no longer any reference to the LTC dispensing requirements in the regulation text. The new requirement does not address when daily cost-sharing amounts would have to be collected from LTC beneficiaries. Thus, LTC pharmacies and facilities may implement consolidated monthly cost-sharing collection irrespective of the cost-sharing methodology assessed on claims. CMS also notes that the majority of Part D enrollees in LTC have no copays.

Valid Prescriptions
CMS will provide coverage for only valid prescriptions in accordance with state law. In addition, CMS does not intend to impose any state law requirements that do not otherwise apply regarding valid prescriptions.

CMS stated their intention was to codify longstanding policy that applicable State law applies in determining what constitutes a valid prescription and that Part D benefits should be available only for drugs that are dispensed upon a valid prescription. CMS did not propose rules governing the conduct of audits by any entities--including plan sponsors, therefore CMS did not address NCPA’s request that Part D plans immediately stop egregious audit practices against pharmacies for violations of requirements that are not in state law.

Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings

- Sponsors are required to offer the annual CMR to targeted beneficiaries in an LTC facility - but when the beneficiary cannot accept the offer to participate - the pharmacist or other qualified provider must perform a CMR without the beneficiary.
- In light of the potential for overlap between monthly DRR and MTM, CMS encourages plan sponsors to consider making arrangements that include the LTC consultant pharmacist in conducting Part D MTM services for targeted beneficiaries in LTC. Such arrangements could include direct contracts between the sponsor and consultant pharmacists (or their intermediaries), or indirect contracts between the sponsor's MTM vendor or PBM and LTC consultant pharmacists (or their intermediaries). CMS is requesting feedback on how such arrangements have improved care coordination or created efficiencies at partd_mtm@cms.hhs.gov.

Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers

- Starting January 1, 2013, a Part D sponsor must submit to CMS only a prescription drug event (PDE) record that contains an active and valid individual prescriber NPI.
- Sponsors are required to do the following:
  - (1) a sponsor must communicate at point-of-sale whether or not the prescriber NPI is active and valid;
  - (2) if the sponsor communicates that the prescriber NPI is not active and valid, the sponsor must permit the pharmacy to confirm that the NPI is active and valid, or in the alternative, to correct it;
  - (3) if the pharmacy confirms that the prescriber NPI is active and valid or corrects it, the sponsor must pay the claim if it is otherwise payable;
  - (4) if the pharmacy cannot or does not correct or confirm that the prescriber NPI is active and valid, the sponsor must require the pharmacy to resubmit the claim (when necessary), which the sponsor must pay, if it is otherwise payable, unless there is an indication of fraud or the claim involves a prescription written by a foreign prescriber (where permitted by State law).
- The back-and-forth between a sponsor and network pharmacy should take no more than 24 hours, which means that sponsors will have to have controls in place to make sure network pharmacies resubmit claims where the sponsor has communicated an issue with the NPI and a pharmacy cannot or does not correct or confirm that the NPI is active an valid.
- In addition, a Part D sponsor must not later recoup payment from a network pharmacy for a claim that does not contain an active and valid individual prescriber NPI, unless the sponsor: (1) has complied with the POS requirements previously described; (2) has verified
that a submitted NPI was not in fact active and valid; and (3) the agreement between the parties explicitly permits such recoupment.

- Approximately 90 percent of Medicare Part D claims as reported in 2011 PDEs submitted to CMS contain valid individual prescriber NPIs, even though CMS permits alternate prescriber IDs at this time.
- Other strategies are being explored which would require prescribers who are not currently required to obtain NPIs to be required to obtain them. CMS states there will be very few instances in which a Part D sponsor would not be able to submit a PDE to CMS due to the lack of an active and valid individual prescriber NPI. In addition, CMS decided against requiring prescribers to enroll in Medicare in order for their prescriptions to be covered by the Part D program because they were concerned about limiting access to medications.
- Of interest, CMS estimates that the annual cost of a contract with a commercial vendor who provides prescriber ID validation services is $160,000. CMS assumes that 80% of the industry needs to acquire additional prescriber ID validation capacity in order to comply with this requirement.