Health Care Communiqué

Q4 2015

UPDATE: CMS PART D PRESCRIBER ENROLLMENT REQUIREMENTS

CMS provided updated information regarding Part D Prescriber Enrollment Requirements during the 2015 Medicare Advantage & Prescription Drug Plan Fall Conference which was held on September 10, 2015.

In an effort to promote quality and combat fraud and abuse, CMS will enforce a new requirement regarding Prescriber Enrollment starting on June 1, 2016. The new regulation will require that all prescriptions to be coverable under Part D, physicians, dentists and other eligible professionals who write Part D drug prescriptions must:

- Be enrolled in Medicare in an approved status, or
- Have validly opted out of Medicare

The Prescriber Enrollment process will allow CMS to validate a prescriber's credentials and will prevent unqualified physicians from prescribing Part D drugs.

Continued...

UPDATE: CMS Part D Prescriber Enrollment Requirements *(Continued)*

CMS will implement exceptions to ensure continuity of care. The exceptions include:

- **Other Authorized Prescribers:** This is an individual other than a physician or eligible professional who is authorized under State or other applicable law to write prescriptions. For example, in some states pharmacists are able to write prescriptions. Medicare statute does not include pharmacists among the types of professionals who can enroll in Medicare. The exception means that Part D beneficiaries can continue to receive their prescriptions written by a pharmacist as allowed by state law, without enrolling or opting out.
- **Provisional Supply:** Part D sponsors must cover a provisional supply of three months before denying future claims due to the prescriber not being enrolled or opted out. This is intended to provide enough time for the prescriber to become enrolled. Provisional supplies are still subject to all other Part D requirements, as prescribed by the prescriber, if allowed by applicable law.

* Prescribers must still have an active and valid individual NPI for prescriptions from an unauthorized prescriber or a provisional supply to be covered.

CMS will implement notice requirements in regards to the Prescriber Enrollment regulation which include:

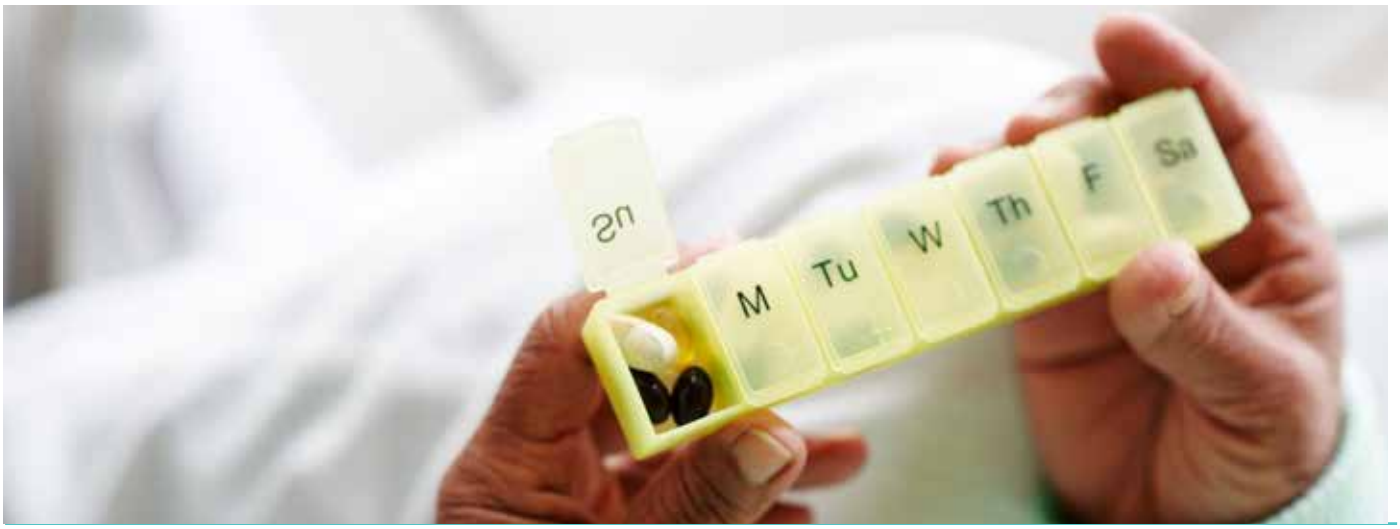
- **Beneficiary Notice:** individual written notice that conforms to CMS requirements will be required within three business days of the adjudicated claim.
- **Prescriber Notice:** Reasonable effort must also be made to notify the prescriber.

CMS is encouraging Part D sponsors to conduct prescriber outreach no later than January 1, 2016. CMS has drafted a prescriber outreach communication which is currently being reviewed based on feedback that was requested. CMS will be issuing a final version of the sample prescriber outreach letters in the near future. In addition, CMS states enrollee outreach can begin no earlier than April 1, 2016 and will depend on trends observed from prescriber outreach that is conducted. CMS will provide additional guidance related to enrollee outreach during 4th quarter 2015.

Plans should be monitoring and tracking the percentage of enrolled prescribers to determine the impact on their enrollees. Part D sponsors should target outreach to those prescribers who have not yet enrolled. Outreach strategies can include:

- Partnering with prescriber organizations to maximize reach and capacity
- Targeting top prescribers with personal outreach such as phone or email
- Providing guidance to prescribers so they can successfully enroll
- Digital advertising
- Specialty events (i.e. stakeholder meeting, conferences, etc.)
- Direct mail
- Customer service scripting

The Prescriber Enrollment initiative will allow CMS to validate a prescriber's credentials and avoid potential fraud and abuse. Part D sponsors should be actively monitoring the progress of enrolled prescribers to minimize negative impact to their enrollees.

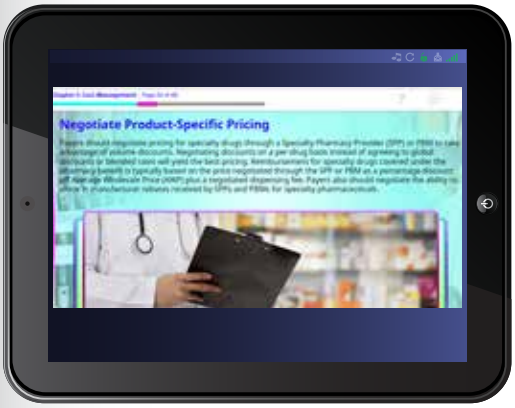


CMS PROGRAM AUDIT UPDATES: 2015 AND 2016

On September 10, 2015, CMS conducted the Medicare Advantage & Prescription Drug Plan Fall Conference & Webcast, and as part of the conference. CMS had a session on 2015 and 2016 Program Audit updates. CMS stated that they have done 16 Program Audits so far in 2015 and the final two audit notices were to be delivered on September 14, 2015. CMS listed a few changes to the 2015 Program Audit protocols based on feedback during the audit process so far this year. CMS confirmed that they will be updating the 2015 Audit Protocols in September 2015 and that these updated protocols will be the standards used for the 2016 Program Audits.

CMS admitted that the original 2015 Audit Protocols that were released in February 2015, contained some data elements that caused confusion across the board for Plans audited in 2015. Based on this feedback, CMS will be reissuing the audit protocols in September 2015, and they will be using the updated version for Program Audits conducted in 2016. CMS has also changed the scoring for the universes data reviews which was a new methodology in 2015. Based on audit experience, CMS has backed off the scoring of ICARs (2 points per condition) for those universes that were not correct after three submissions. Instead, CMS will be issuing an IDS scoring methodology in 2016 to specifically address data issues within the universes. The IDS findings will be equivalent to 1 point per condition similar to the current CAR scoring methodology. Another change CMS has implemented based on 2015 audit feedback is they are no longer requiring the Beneficiary Impact Analysis (BIAs) for instances of self-disclosures and self-identified issues. The final change to come out of the conference is the highly anticipated MTM and Provider Access Pilot Audit protocols will not be rolled out until the 2016 audit season.

During the presentation, CMS reiterated their position that Plans and their delegated entities need to be familiar with the protocols. CMS again, stressed the need for Plans to be conducting ongoing Mock Audits to confirm that they are not only prepared for a Program Audit but are proactively auditing to identify and correct issues as part of these audits. With CMS making the decision to use the same protocols for 2015 and 2016, this allows Plans more flexibility in conducting these audits.



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 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.

MEDICARE PART D MEDICATION THERAPY MANAGEMENT (MTM)

MTM 2016 STAR CUT-POINTS: *Is it all about Stars?*

Background

Medication Therapy Management (MTM) is a required service in the Medicare Part D benefit as part of the Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The Act includes a provision for pharmacists and other qualified health care professionals to deliver MTM services to Medicare beneficiaries at high risk for medication-related problems.[1] The purpose of MTM is to ensure that all medications are used safely and effectively, thereby improving patient outcomes and lowering overall health care costs. When this law was first implemented, the Centers for Medicare and Medicaid (CMS) had a broad vision for MTM, but did not initially define minimum requirements. Since then, there has been development and continued discussion about what the best performance measures should be.

Recognizing the need for a common vision for MTM within pharmacy, eleven national pharmacy organizations developed a consensus definition for MTM services in 2004. MTM is defined as "A service or group of services that optimize therapeutic outcomes for individual patients. Medication therapy management services include medication therapy reviews, pharmacotherapy consults, anticoagulation management, immunizations, health and wellness programs and many other clinical services. Pharmacists provide medication therapy management to help patients get the best benefits from their medication by actively managing drug therapy and by identifying, preventing and resolving medication-related problems."[2]

CMS first published specific MTM requirements beyond the definition above in the 2010 Call Letter. This included instructions for enrollment methods, targeting procedures, and MTM services. Over the next several years, CMS derived information from MTM applications, plan-reported data, exploratory research on MTM, informal interviews with Part D sponsors, and other relevant literature and data. This information is being used to continuously improve the MTM and Sponsors are expected to do the same.

MTM 2016 STAR CUT-POINTS: Is it all about Stars? *(Continued)*

MTM Program Requirements 2016

Following the definition are some standard requirements set forth by CMS. CMS requires sponsors to have an MTM program that:

1. Ensures optimum therapeutic outcomes for targeted Beneficiaries through improved medication use
2. Reduces risk of adverse events
3. May be furnished by pharmacists or other qualified providers
4. May distinguish between services in ambulation and institutional settings
5. Is developed in cooperation with licensed and practicing pharmacists and physicians
6. Each program must include:
   a. Prescriber interventions
   b. Interactive comprehensive medication reviews (CMR)
   c. Written summary of service in CMS' standardized format, frequent monitoring; and
   d. Follow-up of beneficiary medication therapies through Targeted Medication Reviews (TMR) at least quarterly.

Comprehensive Medication Reviews (CMR) are interactive, person-to-person or tele-health medication review of a beneficiary's medications performed by a pharmacist or other qualified provider. CMRs must be performed at least annually. Although plan sponsors can offer MTM services to all of their beneficiaries, they MUST offer them to those who meet CMS's criteria of having multiple chronic diseases, are taking multiple Part D Drugs, and are likely to incur an annual part D cost of $3,507. Plans have some flexibility on which diseases and the number of drugs required for targeting but they must apply the eligibility rules to their Part D population at least quarterly. Medicare Part D plans sponsors are required to enroll targeted beneficiaries using an Opt-out method only. This means the members who are eligible to receive MTM benefits based on the sponsors criteria are all considered enrolled in MTM unless the beneficiary specifically refuses the service. In fact, beneficiaries who continue to be eligible year over year need to be auto-enrolled early in the next program year to promote continuity of care. In addition, plan sponsors are required to offer beneficiaries a CMR within 60 days of enrollment into the program. CMS expects plan sponsors to ACTIVELY engage targeted beneficiaries by using more than one approach to outreach.3

Even with the consensus definition and CMS defined program requirements, not all MTM services will look exactly alike. The value of MTM is determined by the quality of the interventions from the MTM provider. The communication of appropriate information to the prescriber or other health care professional is integral to the intervention component of the MTM service model.[3,4]

MTM 2016 STAR CUT-POINTS: Is it all about Stars? *(Continued)*

Table 1: CMR Completion Rate Star Cut-points for 2016

TYPE	1 Star	2 Star	3 Star	4 Star	5 Star
MA-PD	<13.6%	≥13,6% to <36.2%	≥36.2% to <48.6%	≥48.6% to <76.0%	≥76.0%
PDP	<08.5%	≥08.5% to <16.6%	≥16.6% to <27.2%	≥27.2% to <36.7%	≥36.7%

MTM Services and Quality: CMR Completion Rate (Cut-Points for 2016 Stars)

CMS rates Medicare Part D plans using a star rating system, from 1 star to 5 stars based on their performance and quality. Several factors are taken into consideration when determining the star rating. The 2016 Call Letter states that CMS will add ***"Medication Therapy Management Program Completion Rate for Comprehensive Reviews"*** as a new measure to the 2016 Star Ratings.[15] This measure is based on the Pharmacy Quality Alliance (PQA) endorsed measure and is weighted 1x as a process measure with a minimum denominator of 31.[16] This measure is used to calculate the percentage of beneficiaries who met the eligibility criteria for the Medication Therapy Management (MTM) program and who received a CMR with a written summary in CMS standardized format. The measure includes beneficiaries in the Long Term Care settings, but not those who are in Hospice.

The recently published cut-points for 2016 have put pressure on Part D Sponsors as the CMR rates needed to achieve 4 or 5 star are higher than what the industry expected.[16]

While an administrative metric is important to focus on, it does not address the quality and related outcomes of the service itself. EGWPs and PDP plans do have lower CMR rates to reach however, they too should think about the additional considerations. There are numerous initiatives underway to further define and measure the quality of MTM services. The intention is for these initiatives to ultimately lead to the development of standard methods of measurements for quality. Studies have shown pharmacist-led medication management improve clinical outcomes and reduces overall costs.[5-14] Currently, CMS does expect Part D Sponsors to have processes in place to measure, analyze, and report the outcomes of their MTM programs. Outcomes include whether or not goals of therapy have been reached, and number of successful resolutions to drug therapy recommendations, and beneficiary and provider beneficiary satisfaction. MTM can also serve as an effective method to improve adherence to chronic medications, reduce the use of high risk medications in the elderly population, and optimize diabetes treatment which are part of the Medicare Part D Star measures.

It is clear the MTM is deemed as an integral part of Medicare Part D and CMS will likely continue putting emphasis on this. However, when we look back to the original intent of why MTM was added to the Part D benefit, we need to think about how we can maintain the quality of MTM services to achieve economic, clinical and humanistic outcomes as we try to reach CMR completions rates to reach 5 star.

CMS Definition for CMR Completion Rate:

$$\frac{\text{(Number of beneficiaries included in the denominator who received a CMR during the reporting period)}}{\text{(Number of beneficiaries who were at least 18 years or older as of the beginning of the reporting period and who were enrolled in the MTM program for at least 60 days during the reporting period)}}$$

MTM 2016 STAR CUT-POINTS: Is it all about Stars? *(Continued)*

SBG Perspective

SBG recommends Medicare Part D sponsors to assess their MTM performance as it relates to the Medicare Part D stars, specifically for CMR rates and quality of services. If the plan sponsor is utilizing a team in house, it is a good time to assess if your MTM team is meeting your MTM needs in terms of cost, quality, compliance, and efficiency.

For plans sponsors who delegate this service, whether through the PBM or a vendor, it is important to assess your contract terms to ensure your MTM needs will be met under Medicare Part D.

Some terms to consider include:

- CMR completions rate
- HPMS data submission accuracy
- Timeframe of CMR offered
- Reporting timeliness
- Member Satisfaction

SBG would like to highlight that MTM audits are currently being piloted by CMS. Your assessment of your program should include understand the capabilities and preparedness for audits.[17]

In addition, ensure ability to accurately report all data CMS technical specifications. Plan Sponsors who do not achieve at least a 95% score under Part D Data Validation will be counted as 1 star for MTM. This highlights the importance of oversight and reporting capabilities.

Additional things to consider:

- Effectiveness of engagement and communication towards beneficiaries and providers
- Frequency of Target Medication Reviews (TMR)
- Beneficiary and Provider Satisfaction
- For delegated services, proper oversight and monitoring processes
- Timely and appropriate care coordination
- Long Term Care (LTC) strategies
- Clinical credentials and cultural considerations

Most Importantly, Part D Plan sponsors have an opportunity to look at MTM with a new perspective, less so as a CMS mandated regulation, but as an avenue to help manage the health of beneficiaries which in turn reduces overall costs while improving quality.

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THE LITTLE PINK PILL

Flibanserin (Addyi™)

Key Point Summary

Flibanserin (Addyi™) – made by Sprout Pharmaceuticals and acquired by Valeant on 8/20/2015 in $1 billion acquisition deal.[5]

- Is indicated as a treatment of low sexual desire in women with premenopausal hypoactive sexual desire disorder (HSDD).
- Has minimal efficacy in increasing the sexual activity of women with hypoactive sexual desire disorder.
  - In clinical trials, women reported a difference of one additional sexual event per month (on average) than those receiving no medication.
  - Efficacy of Addyi™ in increasing a woman's "sexual desire" was inconsistently demonstrated in clinical trials. (This was largely dependent on how this was measured in the clinical studies).
- Needs to be taken every day at bedtime and could take several weeks to become effective. (Poor adherence can potentially impact its overall effectiveness).
- Has numerous safety concerns, which include unsafe drops in blood pressure, fainting, and nausea.
- Has drug-drug interactions with common medications often concomitantly prescribed for premenopausal women (e.g. oral contraceptives) that may predispose them to a higher risk of side effects while taking Addyi™.

Payers are encouraged to:

- Check their benefit contracts to determine if treatment of hypoactive sexual desire disorder (HSDD), the condition which Addyi™ uses, falls under those conditions which are considered a contract exclusion.
- If deemed a coverable benefit, apply utilization management review and coverage criteria that is consistent with FDA labeling, REMS program requirements (e.g., prescribing, dispensing and education provided to members by certified prescribers and pharmacies trained on the safety aspects of Addyi™), and maximum dosing limits to ensure safe and appropriate use.

Background

- On August 18, 2015, the FDA approved Addyi™ made by Sprout Pharmaceuticals for the treatment of "generalized hypoactive sexual desire disorder" (HSDD) – a low sexual desire with no apparent cause in women who have not yet gone through menopause.[1]
- The target female population with HSDD in the U.S. is estimated at 16 million women.
- Annual sales of Addyi™ are projected to reach as high as $2 billion, depending on how successful Sprout Pharmaceuticals is able to market its product among prescribers and the general public.[2]
- Although Addyi™ is the only option approved to treat HSDD, it will largely compete with Viagra® and other medications such as Cialis® and Levitra® (used in male impotence and erectile dysfunction), as an alternative potential option for the female sex partner.

How Does Addyi™ Work?

- Unlike Viagra®, which works by increasing blood flow to the genitals, Addyi™ works very differently by influencing the woman's brain chemistry and serotonin and dopamine levels associated with mood and appetite.[1] This causes a tendency to increase the sex drive.
- The actual mechanism by which Addyi™ works, is not fully known.[1]

Estimated Cost of Addyi™

- While the exact price of Addyi™ is not yet known, it is speculated that its cost will be fairly comparable to a month's supply for 10 Viagra® pills at a cost of about $400 per month.[3]
- Gauging a true monthly cost comparison of Addyi™ to Viagra® and/or other erectile dysfunction medications is challenging, since erectile dysfunction medications are taken on an as-needed basis and will also depend on the quantity limits that payers apply and/or cover per month. This is in contrast to Addyi™, which needs to be taken every day to be effective and thus supporting up to 30 pills dispensed on a chronic basis.[1]

THE LITTLE PINK PILL – *Flibanserin (Addyi™) (Continued)*

Addyi™ – The Long Road to FDA Approval

Addyi™ originally started as a medication under research as an antidepressant by Boehringer Ingelheim, but was found to lack efficacy for this use. The manufacturer decided to drop the compound after its failed attempt to gain FDA approval for its use in women with HSDD.

- In 2009, the FDA Advisory Panel unanimously rejected Addyi™ approval concluding that:[4]
  - While Addyi™ was effective in increasing the number of satisfying sexual experiences or events (SSEs), by an average of 1.7 more events per month, it did NOT improve sexual desire.
  - Placebo alone also increased SSEs by 1.0 per month (from 2.7 to 3.7), and a net incremental benefit with Addyi™ of 0.7 SSEs. (This translates to a small benefit of just one extra SSE per month compared to no treatment).
  - Safety risks (unsafe drops in blood pressure, dizziness) may outweigh benefits.
- In 2010, Sprout Pharmaceuticals secured the rights to Addyi™. Their success in gaining FDA approval of Addyi™ was largely driven by the FDA's reevaluation of clinical trial and safety information over a course of five years and strong influence of public outcry on the disproportionate number of FDA medications approved for male sexual dysfunction versus those (none) available for women.

Addyi™ Safety Risks

Approval of Addyi™ comes with a strict Risk Evaluation and Mitigation Strategy (REMS) requirement to monitor and guard against safety risks associated with the medication.

- Addyi™ can cause severely low blood pressure and loss of consciousness.
- Fatigue, nausea, dizziness, sleepiness, insomnia and dry mouth are also common side effects.
- Risks of adverse events are increased and can become more severe when patients drink alcohol or when taking certain other medicines (such as oral contraceptives) or other medications that can increase amounts of Addyi™ circulating in the blood.
- Due to these risks, the FDA is requiring that Addyi™ prescriptions are:
  - Prescribed by only "certified" physicians who must complete a manufacturer sponsored course on Addyi™ and counsel patients, and
  - Filled only by certified pharmacies trained on the drug's risks.

SBG Perspective

While Addyi™ provides an option for an "unmet" need for a condition (HSDD) that has no currently available treatment options, the condition itself may be one that most payers may not generally cover under their benefit contracts. SBG recommends that Payers:

- Check their benefit contracts and contract exclusion language to determine how Addyi™ should be handled for coverage (e.g., contract exclusion versus covered benefit for a medically necessary condition). While controversial, the condition for which Addyi™ is intended to treat may not be covered by member benefit contracts, regardless of medical necessity.
- If no benefit exclusion language may be applicable and payer determines that Addyi™ is a covered benefit, utilization management should be considered to ensure safe and appropriate use that is consistent with FDA labeling and REMS program requirements for Addyi™. This may include:
  - Confirmation of diagnosis of generalized hypoactive sexual desire (HSDD), including medical records documenting work-up and that condition is NOT due to:
    - Co-existing medical or psychiatric condition
    - Problems within the relationship
    - The effects of a medication or other drug substance.
  - Use in premenopausal females only
  - Confirmation that all REMS program requirements are followed (e.g., prescribing and dispensing of Addyi™ by only certified prescribers and certified pharmacies that have enrolled and completed training requirements, verification that the Patient-Provider Agreement Form informs the patient about the increased risk of severe hypotension and syncope and about the importance of not drinking alcohol during treatment with Addyi™)
  - Quantity level limit of 30 tablets (30-day supply)

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CMS TIMELINE:

Nov. – Dec, 2015	CMS issues "close out" information and instructions to MA plans, MA-PD plans, PDPs, and cost-based plans that are non-renewing or reducing service areas
Dec. 1, 2015	Enrollees in Medicare cost-based plans not offering Part D must receive the combined ANOC/EOC Cost-based plans must publish notice of non-renewal
Dec. 7, 2015	End of the Annual Election Period
Mid-Dec, 2015	Display measures data on cms.gov updated
Dec. 31, 2015	Deadline for D-SNPs and MMPs that separated the ANOC from the EOC to provide the EOC to enrollees
Beginning Jan, 2016	CMS is requiring that the facilitator send Nx and FIR reports only to the Part D sponsor
Jan 1, 2016	Plan Benefit Period Begins
Early Jan, 2016	Release of CY 2017 MAO/MA-PD/PDP/SAE/ EGWP applications
Mid Jan, 2016	Industry training on CY 2017 applications
Jan. 1 – Feb. 14, 2016	Annual 45-Day Medicare Advantage Disenrollment Period (MADP)
Late Feb, 2016	Applications due for CY 2017

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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®. In addition, UL offers a talent management suite that provides companies the ability to improve workforce skills & competencies within established role-based talent training programs to drive business performance.

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, 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 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
- Compliance Medicare/Medicaid
- PBM Auditing
- Specialty Pharmacy Management Strategy
- Clinical Consulting

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