Each edition of the IHCA Regulatory Beat will feature focus articles on specific regulatory topics. If you have a topic you’d like to see covered here, please let us know!

Proposed CMS Rulemaking – Part 6
The October 14, 2015 deadline for comments to the CMS proposed rulemaking, which significantly revises the entire set of requirements for Long Term Care Facilities, has passed. CMS received over 9,000 comments to these proposed rules. CMS will now be required to review all of the comments and decide what changes need to be made before they can adopt the rules as a final rulemaking to be published in the Federal Register. CMS has three years from the date of proposed rulemaking to finalize and adopt rules. After final adoption, CMS will then need to revise the Interpretive Guidelines to clarify the final rulemaking.

Over the next several issues of Regulatory Beat, I will continue with my section by section review of the CMS proposed regulations. It is important that you are aware and review the proposed regulations before they are adopted. CMS believes these proposed changes are necessary to reflect the substantial advances that have been made over the past several years in the theory and practice of service delivery and safety. These proposals are also an integral part of CMS’s efforts to achieve broad-based improvements both in the quality of health care furnished through federal programs, and in patient safety, while at the same time reducing procedural burdens on providers.

This segment will focus on Pharmacy Services (483.45); Laboratory, Radiology, and Other Diagnostic Services (483.50); and Dental Services (483.55).

M. Pharmacy Services (483.45)
Currently, the LTC requirements require that each resident’s drug regimen be reviewed by a pharmacist at least once a month. Based on CMS’s experience with LTC facilities, some pharmacists review the medical chart for each resident when they perform the drug regimen review, and others simply review the medication administration record (MAR). CMS believes that having the pharmacist review residents’ medical charts when medications are prescribed would not only assist the pharmacist in detecting irregularities related to certain drugs but also enhance or contribute to the goal of ensuring that medications are used only when medically appropriate for the resident. CMS also believes that the pharmacist’s review could contribute to their proposed requirements for infection control and antibiotic stewardship.

c)(2) New requirement that a pharmacist be required to review the resident’s medical record coincident with the drug regimen review when –
   i) the resident is new to the facility;
   ii) a prior resident returns or is transferred from a hospital or other facility; and
   iii) during each monthly drug regimen review when the resident has been prescribed or is taking a psychotropic drug, antibiotic or any drug the QAA Committee has requested be included in the pharmacist’s monthly drug review.
c)(3) Revise the definition of psychotropic drug to include the following categories
   i) anti-psychotic;
   ii) anti-depressant;
   iii) anti-anxiety;
   iv) hypnotic;
   v) opioid analgesic; and/or
   vi) any other drug that results in effects similar to the drugs listed above that affect brain activities
       associated with mental processes and behavior.

c)(4) New requirement that the pharmacist must report any irregularities to the attending physician, facility’s
     medical director and director of nursing, and these reports must be acted upon. The pharmacist must create a
     written report that is dated, and contains, at a minimum, the resident’s name, the relevant drug and the irregularity
     the pharmacist noted. The attending physician must document in the resident’s medical record that the identified
     irregularity has been reviewed and what, if any, action has been taken to address it. If there is to be no change in
     the medication, the attending physician should document his or her rationale in the resident’s medical record.

d) Revised language regarding each resident’s drug regimen must be free from unnecessary drugs and what an
   unnecessary drug is.

e) New language that LTC facilities ensure that residents do not receive psychotropic drugs pursuant to a PRN order
   unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record.
   Also, every PRN order for a psychotropic drug is limited to 48 hours and cannot be continued beyond that time
   unless the resident’s primary care provider documents the justification/rationale for this continuation in the
   resident’s clinical record.

f) CMS is relocating the medication errors requirements into the Pharmacy Services section.

CMS believes that the above proposed requirements should not discourage the use of psychotropic medications
when these drugs are required for the resident’s benefit, however, the increased documentation requirements will
be problematic from a provider’s perspective.

N. Laboratory, Radiology, and Other Diagnostic Services (483.50)
This is a new section that combines all of the laboratory, radiology and other diagnostic services under one section.

a)(2)(i) Revised by removing “attending physician” and replacing it with “a physician, a physician assistant, nurse
       practitioner, or clinical nurse specialist” to allow laboratory, radiology and other diagnostic services to be
       ordered by these practitioners in accordance with state law. These revisions would increase access to care by
       avoiding possible delays in treatment of residents as well as eliminate burden to attending physicians by clarifying
       the services that non-physicians practitioners can provide.

a)(2)(ii) Clarify that the laboratory must promptly notify the ordering professional if results fall outside of clinical
         reference or expected “normal” ranges.

b)(2)(ii) Revised to allow for increased flexibility to provide that other practitioners have the ability to receive
         laboratory, radiology and other diagnostic results if these practitioners ordered the tests.

O. Dental Services (483.55)
CMS recognizes that dental care supports the overall well-being of all facility residents. CMS also recognizes that
Medicare does not cover certain dental services such as the care, treatment, filling, removal, or replacement of
teeth or structures directly supporting teeth and that State Medicaid Plans vary in coverage of dental services.
a)(3) New requirement that a facility may not charge a resident for the loss of or damage to dentures when the loss or damage is the responsibility of the facility. CMS does not define or specify what the responsibility of the facility is.

a)(4) Revised by adding the phrase “or if requested” to clarify that if a resident asks for assistance in scheduling a dental appointment, the facility would be required to provide the assistance.

a)(4)(ii) Revised by adding language requiring facilities to arrange for transportation to and from the dental service location.

a)(5) New requirement that would require the facility to do a dental referral within three business days or less from the time of loss or damage to dentures is identified, unless the facility can provide documentation of extenuating circumstances that resulted in the delay.

Similar changes in (a) made to (b).

The next edition of Regulatory Beat will focus on Food and Nutrition Services (483.60), Specialized Rehabilitative Services (483.65), and Outpatient Rehabilitation Services (483.67).

CDC Recommends All Nursing Homes Implement Core Elements to Improve Antibiotic Use

Urged to implement at least one core element immediately

New recommendations from the Centers for Disease Control and Prevention (CDC) advise all nursing homes to improve antibiotic prescribing practices and reduce their inappropriate use to protect residents from the consequences of antibiotic-resistant infections, such as *C. difficile*.

To guide these improvements, CDC released a new resource: *Core Elements of Antibiotic Stewardship for Nursing Homes*. The Core Elements for Nursing Homes expand upon CDC’s recommendation last year that all acute care hospitals implement an antibiotic stewardship program designed to optimize treatment of infections while reducing adverse events associated with antibiotic use.

Approximately 4.1 million Americans are admitted to or reside in nursing homes each year. Antibiotics are the most frequently prescribed medications in nursing homes. Up to 70 percent of residents receive one or more courses of antibiotics during a year. Up to 75 percent of antibiotics prescribed in nursing homes are given incorrectly, meaning either the drug is unnecessary or the prescription is for the wrong drug, dose or duration.

"Superbugs that are hard to treat pose a health risk to all Americans, particularly the elderly whose bodies don’t fight infection as well,” said CDC Director Tom Frieden, M.D., M.P.H. “One way to keep older Americans safe from these superbugs is to make sure antibiotics are used appropriately all the time and everywhere, particularly in nursing homes.”

Protecting nursing home residents

The Core Elements provide practical ways for nursing homes to initiate or expand antibiotic stewardship activities. The guide provides examples of how antibiotic use can be monitored and improved by nursing home leadership and staff. The companion checklist can be used to assess policies and practices already in place and to review progress in expanding stewardship activities on a regular basis. However, depending on resources, some facilities may need more time to implement all these important protections. Ultimately, nursing home antibiotic stewardship activities should, at a minimum, include the following:

1. **Leadership commitment:** Demonstrate support and commitment to safe and appropriate antibiotic use.
2. **Accountability:** Identify leaders who are responsible for promoting and overseeing antibiotic stewardship activities at the nursing home.
3. **Drug expertise:** Establish access to experts with experience or training in improving antibiotic use.
4. **Action:** Take at least one new action to improve the way antibiotics are used in the facility.

5. **Tracking:** Measure how antibiotics are used and the complications (e.g., *C. difficile* infections) from antibiotics in the facility.

6. **Reporting:** Share information with healthcare providers and staff about how antibiotics are used in the facility.

7. **Education:** Provide resources to healthcare providers, nursing staff, residents and families to learn about antibiotic resistance and opportunities for improving antibiotic use.

“We encourage nursing homes to work in a step-wise manner implementing one or two activities at first, then gradually adding new strategies from each core element over time,” said Nimalie Stone, M.D., CDC medical epidemiologist for long-term care. “Taking any of these actions to improve antibiotic use in a nursing home will help protect against antibiotic-resistant infections and more effectively treat infections. This could lead to better recoveries from infections and ultimately improve health outcomes for all residents.”

The Centers for Medicare & Medicaid Services (CMS) recently proposed a rule that would require long-term care facilities to incorporate an antibiotic stewardship program, including antibiotic use protocols and antibiotic monitoring, into their infection prevention and control program. According to CMS, these requirements will decrease unnecessary or inappropriate antibiotic use by ensuring that residents who need antibiotics are prescribed the right drug at the right dose for the right duration.

“The nursing homes that engage in antibiotic stewardship improve care for residents and help reduce antibiotic resistance,” said Patrick Conway, M.D., M.Sc., CMS deputy administrator for innovation and quality & CMS chief medical officer.

The release of CDC’s Core Elements for Nursing Homes is one step in achieving the objectives set out in the National Action Plan for Combating Antibiotic-resistant Bacteria. Investments to improve antibiotic stewardship across all settings are part of CDC’s Antibiotic Resistance Solutions Initiative for fiscal year 2016.

As part of the plan, within three years CDC will provide technical assistance to federal facilities (e.g., those operated by the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service) and other large health systems to scale up implementation and assess interventions to improve outpatient antibiotic prescribing, extend effective interventions to long term care settings, and ensure long-term sustainability of antibiotic stewardship efforts.

To learn more about the Core Elements of Antibiotic Stewardship for Nursing Homes, visit: [http://www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html](http://www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html).

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**Trending Statistics**

*Each issue of Regulatory Beat features an interesting statistic or trend in the long term care regulatory arena.*

**Partnership to Improve Dementia Care in Nursing Homes**

**Antipsychotic Drug use in Nursing Homes Trend Update**

The National Partnership to Improve Dementia Care in Nursing Homes is committed to improving the quality of care for individuals with dementia living in nursing homes. The Partnership has a mission to deliver health care that is person-centered, comprehensive and interdisciplinary with a specific focus on protecting residents from being prescribed antipsychotic medications unless there is a valid, clinical indication and a systematic process to evaluate each individual’s need. CMS promotes a multidimensional approach that includes; research, partnerships and state-based coalitions, revised surveyor guidance, training for providers and surveyors and public reporting.
CMS is tracking the progress of the Partnership by reviewing publicly reported measures. The official measure of the Partnership is the percentage of long-stay nursing home residents who are receiving an antipsychotic medication, excluding those residents diagnosed with schizophrenia, Huntington’s Disease or Tourette’s Syndrome. In 2011Q4 23.9 percent of long-stay nursing home residents were receiving an antipsychotic medication; since then there has been a decrease of 24.8 percent to a national prevalence of 18.0 percent in 2015Q2. Success has varied by state and CMS region, with some states and regions having seen a reduction of greater than 20 percent.

A three-quarter measure is posted to the Nursing Home Compare website at www.medicare.gov/nursinghomecompare. The long-stay measure on Nursing Home Compare, is the exact same measure as below, except each facility’s score is averaged over the last three quarters in order to give consumers information on the past history of each facility. For more information on this National Partnership, please send correspondence to dnh_behavioralhealth@cms.hhs.gov.

Click here for the full summary. Illinois is still ranked 49th with a percentage rate of 22.08 percent which is a 3.62 percent point decrease from 2011Q4 - 2015Q2 with an overall percent change decrease of 14.1 percent. We can do better and we can expect that IDPH and CMS surveyors will be focusing on this issue during annual LTC surveys in Illinois for the for-see-able future.

The Eden Alternative has received a federal grant to provide Dementia Beyond Drugs training for FREE in several states including Illinois. IHCA endorsed their grant proposal two years ago and as a co-sponsor, we’d like for you to click here to register for this program. There is VERY limited seating, so sign up today!

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**Important Rules, Regulations & Notices**

1) There were no federal Survey and Certification (S&C) Letters released since the October 13 edition of *Regulatory Beat*.

2) Federal CMS/HHS released several notices/announcements since the last issue of *Regulatory Beat*. They include:

- **ICD-10 Information/Updates**
  - Learn How to Assign an ICD-10-CM Diagnosis Code with MLN Connects Videos
  - Video Slideshow from August 27 MLN Connects Call Available
  - 5 Ways to Check Your Claim Status
  - Contact List for ICD-10 Questions
  - ICD-10 Ombudsman and ICD-10 Coordination Center Support Your Transition Needs
  - Qualifiers for ICD-10 Diagnosis Codes on Electronic Claims
Medicare Learning Network (MLN) Educational Products

- "Infection Control: Environmental Safety" Web-Based Training Course — Released
- "Infection Control: Injection Safety" Web-Based Training Course — Released
- “PECOS for Provider and Supplier Organizations” Fact Sheet — Revised

CMS Manual System – Transmittal 149 – For all types of Providers and Suppliers Subject to Certification (click here). Clarification is being provided for all providers and suppliers subject to certification as to the meaning of the terms “marriage,” “spouse,” and other terms that implicate the spousal relationship wherever used in the appendices.

3) The Illinois Department of Healthcare and Family Services (HFS) issued one informational Notice since the last issue of *Regulatory Beat*. It was:

- IMPACT Webinar Series Release for rural health providers, ambulance providers and non-ambulance services transportation providers (http://www.illinois.gov/hfs/impact/Pages/webinars.aspx).

4) List of upcoming Telligen events can be found here (http://www.telligenqinqio.com/).

5) The U.S. Food and Drug Administration (FDA) recently granted accelerated approval to Praxbind (idarucizumab) for use in patients who are taking the anticoagulant Pradaxa (dabigatran) during emergency situations when there is a need to reverse Pradaxa’s blood-thinning effects (click here).

6) The Association of Standardized Patient Educators (ASPE) recently sent to AHCA/NCAL their Compendium of Residential Care and Assisted Living Regulations and Policy (see below).

   - Executive Summary
   - Full Compendium
   - State Summaries

7) HealthDay recently published two articles of interest. They were:

   - **Medical Gowns, Gloves Often Source of Contamination: Study** - But researchers say that education and practice can dramatically improve health care worker hygiene. For the study, workers at four Ohio hospitals simulated gown and glove removal. Additional health care workers from a separate facility participated in a program that included education and practice of removing contaminated gowns and gloves. The health care workers simulated 435 gown and glove removals. The researchers used a fluorescent lotion to determine "contamination." Skin or clothing got contaminated 46 percent of the time, the investigators found. But, the education and practice program led to a significant drop in the contamination rate -- from 60 percent to about 19 percent, the findings showed.

   - **Infections, Not Clumsiness, Cause Many Falls** - Illness can lower blood pressure, lead to dizziness, researchers say. People arriving at the emergency room for a fall may be there due to an underlying infection rather than clumsiness, a new study suggests. Infection-related falls usually affect older people but can happen to anyone, researchers from Massachusetts General Hospital warn.

8) The New York Times recently published an article entitled, “New Approach Advised to Treat Schizophrenia.” More than two million people in the United States have a diagnosis of schizophrenia, and the treatment for most of them mainly involves strong doses of antipsychotic drugs that blunt hallucinations and delusions but can come with unbearable side effects, like severe weight gain or debilitating tremors. Now, results of a landmark government-funded study call that approach into question. The findings, from by far the most rigorous trial to date conducted in the United States, concluded that schizophrenia patients who received smaller doses of antipsychotic medication and a bigger emphasis on one-on-one talk therapy and family support made greater strides in recovery over the first two years of treatment than patients who got the usual drug-focused care.
9) **Medical News Today** recently published two articles of interest. They were:

- **Depression: Not a Normal Part of Aging.** Health problems, reduced income and the death or a partner or loved one are just some of the difficulties often faced in older age. With this in mind, it is perhaps unsurprising that around 7 million American adults aged 65 and older experience some form of depression. What is surprising is that depression among seniors is often overlooked and untreated.

- **Common Breast Cancer Drug Could Help Tackle MRSA.** Antibiotic resistance is a growing concern across the globe; last year, the World Health Organization warned that we are heading toward a "post-antibiotic era" unless more is done to tackle the problem. Now, researchers find that an existing drug used to treat breast cancer may be effective against one of the most common superbugs: MRSA.

10) **Medicalxpress** recently published an article entitled, “**Determining Accurate Life Expectancy of Older Adults Requires Provider, Patient Discussion.**” Health care providers must have detailed discussions with their older adult patients to better determine their true life expectancy, as older adults do not accurately predict their own prognosis, a key factor in making decisions about future health interventions, according to researchers at UC San Francisco and San Francisco Veterans Affairs Medical Center.

11) **HealthData Management** published an article entitled, “**New Details Emerge on HIPAA Audits.**” The HHS Office for Civil Rights will begin Phase 2 of its long-awaited audit program in early 2016 to determine compliance of covered entities and business associates with HIPAA privacy, security and breach notification rules.

12) **McKnight’s** had several articles of interest. They include:

- **CDC: 3 in 4 Nursing Home Prescriptions are Wrong.** Up to 75 percent of antibiotics prescriptions given to nursing home residents are unnecessary or incorrectly prescribed, the CDC and Prevention claims. A new report from the Wall Street Journal cites CDC statistics indicating a majority of nursing home residents receive one or more courses of antibiotics each year to treat common conditions such as urinary tract infections, pneumonia and cellulitis. But up to 75 percent of those prescriptions are either unnecessarily prescribed, or for the wrong drug, dose or duration.

- **Patient SNF Choice Still Reigns in Bundled Payment Model.** Despite the heavy emphasis on partnerships between skilled nursing facilities and hospitals participating in a bundled payment program for hip and knee replacements, patient choice should ultimately prevail, experts shared during a McKnight’s webcast on Thursday. Hospitals participating in the CMS Comprehensive Care for Joint Replacement Model have plenty of incentives — including a waiver of the three-day rule — to advise patients on choosing an SNF within a network of trusted providers. But should a patient choose an SNF outside of the hospital’s network, the hospital “cannot stop” the patient, said Elana Levinthal Stair, health director at Avalere, during the webcast.

- **Mortality Rates, Hospital Admissions Higher in For-Profit LTC Facilities.** For-profit long term care facilities have significantly higher rates of mortality and hospital admissions than their not-for-profit counterparts, new research has found. The study examined admissions at 384 for-profit and 256 not-for-profit long term care facilities in Ontario, Canada, between January 2010 and March 2012. One year after admission, the for-profit facilities showed an overall mortality rate of 207.5 residents per 1,000 person-years, compared to a rate of 184 for not-for-profit facilities. The hospitalization rate for for-profit facilities at the one year mark was 462.4 per 1,000 person-years, while the rate for not-for-profit facilities was 358.0.

- **Quadruple-Power Flu Vaccines Reduce Hospitalizations: Report.** Flu vaccines with four times the strength of a regular flu shot may help decrease the rate of flu-related hospitalizations in nursing homes, according to a new study. Results showed that the group that received the stronger vaccine had a 19.7 percent rate of hospital admission, compared to 20.9 percent in the standard group.
• **Geriatrics Society Improves Medication Guidelines For Seniors.** The American Geriatrics Society has released an updated version of the Beers Criteria, a list of medications that are potentially dangerous if prescribed inappropriately to older adults. The Beers Criteria is available online through the *Journal of the American Geriatrics Society*.

• **RACs Recovered $2.4 Billion in Provider Overpayments Last Year: Report.** The Medicare Recovery Audit Program identified and corrected more than 1.1 million claims for improper payments worth $2.57 billion in fiscal year 2014, according to a new CMS report. This included $2.39 billion in overpayments, the majority of which (84 percent) involved hospital inpatients. There was also $173.1 million in underpayments to providers discovered, according the report submitted to Congress. Skilled nursing facilities received $86 million in overpayments, or 4 percent of the improper outlays. There was also around $151,000 restored in underpayments. Regionally, the largest amount of SNF overpayments was in the upper Midwest and West Coast (Region D).

• **Quality Measure Standardization on its Way, CMS Says.** Skilled nursing facilities must standardize six of the eight measure domains laid out by the IMPACT Act to begin in October 2016, CMS officials told providers Wednesday. The *IMPACT Act*, which was signed into law in October 2014, requires skilled nursing facilities, long-term care hospitals, inpatient rehabilitation facilities and home health agencies to submit standardized patient assessment data. Data standardization can move providers toward the “sweet spot” of uniformity, and help patients progress easier through the care continuum, said Tara McMullen, Ph.D., MPH, during an *MLN Connects* provider call.

• **After Three Years, Experts Disagree Whether ACOs are Working.** Health care experts disagree on whether accountable care organizations, now in their third year, are working, according to a new report from *Kaiser Health News*. Accountable care organizations have failed to save Medicare money but improved outcomes for patients, experts said. ACOs generated more than $411 million in savings in 2014, but bonuses paid out to providers left Medicare with a $2.6 million net loss, according to CMS.

• 13) **Interesting Fact:** The practices of *Halloween* mostly come from Celtic paganism in the British Isles, and their feast of Samhain, the new year. They believed it was the time when ghosts and spirits came out to haunt, and the Celts would appease the spirits by giving them treats.