April 19, 2016 Edition

**Feature Focus**

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!

**Summary of the April 13, 2016 Quarterly Long Term Care Provider Association Meeting**

The Illinois Department of Public Health’s (IDPH) Office of Health Care Regulation (OHCR) hosts a quarterly meeting of the LTC Provider Associations to discuss survey issues, get rulemaking updates and answer provider questions. IHCA appreciates the opportunity to have these face-to-face meetings with key OHCR management staff (Darlene Harney and Connie Jensen), which allow for open communication about various LTC issues. The following is a summary of the issues discussed at this meeting:

1) **LTC Electronic Incident Report Form** – LTC providers have been asking for an electronic incident report form and process for a long time. The current system of hand writing incident report forms and faxing them in is inefficient and time consuming. IDPH has been working with the provider associations to develop an electronic form that can be completed and sent electronically to IDPH. IDPH drafted a form and shared it with the LTC Advisory Board a few months ago. IHCA along with others, submitted comments to the draft form. IDPH stated they will bring the revised draft form back to the next LTC Advisory Board Meeting scheduled for May 19, 2016. As soon as the revised form is made available to us, we will share with our members and get your feedback. This new form and process should be a welcome replacement to the current system of reporting incidents.

2) **Informal Dispute Resolution (IDR) Denial Responses** – For many years IDPH has not been following the Nursing Home Care Act with respect to IDR responses. The statute requires IDPH to provide a written explanation of the reason or reasons why the evidence or arguments were insufficient to refute the findings. For whatever reasons, IDPH has not given the written explanation and IHCA proposed legislation this session to strengthen this requirement. IDPH stated, at this meeting, that they have started, as of April 1, 2016, providing written explanations to denied IDRs. IHCA will continue to pursue our legislation to solidify the requirement. IHCA will monitor this closely.

3) **Subpart S Rulemaking/Implementation of Subpart S** – As part of PA 96-1372 (effective 7-29-2010), IDPH was to develop rulemaking to implement the certification of psychiatric care units within LTC facilities for persons with mental illness. To date, these rules have not been proposed. With the change in administrations, the draft rules have been caught up in the Governor’s Office (both Quinn and Rauner). IDPH reported that there is some movement and the Governor’s Office is working with them to get this draft set of rules reviewed and ready for proposal in the Illinois Register for public comment. IDPH has not yet shared their draft externally. As soon as it is available, we will share with our members and draft comments. IDPH hopes that the rulemaking will be ready for the LTC Advisory Board review by the end of the year.
4) Distressed Facility Rulemaking – This is also a requirement under PA 96-1372. IDPH stated that the draft rulemaking to implement this section is under internal discussion and review. This concept is very problematic. IDPH gave no timetable for when these draft rules will be ready for Governor’s Office review and approval prior to taking to the LTC Advisory Board. IHCA will continue to monitor.

5) Informed Consent and Behavioral Unit Rulemaking – These concepts are also required under PA 96-1372. Both of these provisions of the law require the input of the Illinois Department of Health Services (DHS). IDPH stated that discussions are occurring between the two agencies but that they are still a long way off in having an agreed upon draft ready for submittal to the Governor’s Office. No timetable given on these two sets of rules. IHCA will continue to monitor.

6) Medical Marijuana/Cannabis – This is a very complex and confusing area, especially for LTC facilities. Federal law still makes medical marijuana illegal. Even though President Obama stated that DEA will not actively enforce this provision, the law remains unchanged. With the upcoming change in presidency, there are questions on how the new administration will address this. IDPH stated that they are doing research to see if there are any other states or if there are any guidelines available with respect to use of medical marijuana in health care facilities. This issue is problematic for LTC facilities due to the fact that medical marijuana is not a prescription drug, which creates all kinds of possession, storage, usage and liability issues. Until the federal issue is resolved and IDPH drafts rules/guidelines, LTC facilities should be very careful in this area. If a LTC facility is considering allowing use of medical marijuana, they should work very closely with their legal counsel to address the many inherent issues and liability concerns.

7) Electronic Monitoring (Granny Cams) – Until just recently, IDPH stated that they did not feel that rulemaking was necessary to implement this legislation (effective 1-29-16 with the release of the Electronic Monitoring Notification and Consent Form). IHCA and others vehemently disagreed and asked for a meeting of all the interested parties to discuss this issue. A meeting was held with IDPH, the Attorney General’s Office (sponsor of the original legislation), IHCA and other interested parties. It was decided at this meeting that rules are necessary and IDPH was directed to start drafting implementing regulations based on the list of questions/concerns presented by IHCA and others. The law is in effect, so until the rules are filed, LTC facilities only have the statutory language to work under. If a resident/family requests electronic monitoring, a LTC facility should work closely with their legal counsel to draft facility policies to address the shortfalls of the legislation and then correct/modify the policies once the rules are published.

8) A question was raised with respect to nurse aides and if they can connect an oxygen line to a tank or to a wall connection. IDPH stated that this is not allowed under the tasks of a nurse aide. Oxygen is considered a medication and must be administered by a nurse/medical professional. Nurse aides can only provide comfort measures, such as adjusting the cannula.

9) A question was asked with regard to whether the 36 hour course required to be an Activity Director could also count for the first year’s 10 hours of CEUs. IDPH stated that this is not addressed in the regulations, but that they agreed that the 36 hour course could count towards the first year’s CEUs.

10) The LTC Associations asked IDPH about the perception that there seems to be many more onsite follow-up visits. IDPH stated that due to their recent staff increases, they now have staff available to do onsite follow-up visits as opposed to desk reviews. IDPH stated that providers can expect to see more onsite visits to facilities for follow-ups (even “C” levels) and incident reports than in prior years.

11) IDPH also stated that self-reported abuse allegation/investigations are an increased focus for IDPH and staff will be following up onsite verifying that the facility did do an adequate investigation and proper actions were taken. The concept of citations for these self-reports and not sanctions is being discussed internally within IDPH.
12) Section 300.4090(b) requires that Psychiatric Rehabilitation Service Directors attend a Department of Healthcare and Family Services (HFS) training program. However, HFS does not offer such training so IDPH will consider removing this provision from the current rules.

13) F153 (access to resident records) – What is the IDPH interpretation with regard to access of records from deceased or discharged residents? IDPH stated they would need to review this issue and discuss with federal CMS staff, IDPH legal and the IDPH survey supervisors prior to giving us an answer.

14) Post Survey Questionnaire – This form is sent with each CMS 2567 and asks for feedback on the survey conducted by IDPH staff. The answers are kept strictly confidential and are generally used for training purposes. The current form is being revised and they hope to have an electronic version available in the near future.

15) The next round of IDPH Town Hall Meetings is scheduled. These are regional meetings, very informal and an excellent opportunity to ask questions. I strongly urge that staff from each facility attend one of these Town Hall Meetings. Contact the IDPH Regional Office to RSVP due to limited space in some locations.

- 4/27 – The Elms – Macomb 2-4 p.m.
- 5/12 – Marion Regional Office Building – 1-3 p.m.
- 5/26 – Oak Trace – Downers Grove – 1-3 p.m.
- 6/7 - Brookens Building – Champaign – 1-3 p.m.
- 6/29 – Norridge HC and Rehab – 2-4 p.m.
- 7/6 – Washington County Hospital – Nashville – 1-3 p.m.
- 7/20 – Pine Crest Manor – Mt. Morris – 1-3 p.m.
- 8/2 – Hope Creek Care Center – East Moline – 1-3 p.m.
- 8/11 – Hamilton Memorial Rehab – McLeansboro – 1-3 p.m.
- 8/31 – Memorial Education Building – O’Fallon – 1-3 p.m.
- 9/14 – Alden Estates of Shorewood – 1-3 p.m.
- 10/19 – Brookens Building – Champaign – 1-3 p.m.
- 11/15 - Friendship Village – Schaumburg – 10 a.m.-12 noon

16) Question with regard to the provision in the federal budget bill that allows for inflation/increased federal fines. Has federal CMS given any direction on this provision? IDPH stated that federal CMS has not offered any guidance on this provision. The provision states that federal CMS may increase fines based on inflation, but they have not provided any direction to date.

17) Question on IDPH moving towards electronic POCs. IDPH is looking into this and stated it is on their to-do list but not a current priority. We urged IDPH to please move this up on their agenda of things to get done in the near future.

18) Due to problems with budget, IDPH is having mailing issues and delays. IDPH is sending out email notices to facilities that their certified letter is coming, but may be slightly delayed. We raised questions on this impacting timeframes for responses and they stated that they will have to look into this, talk to IDPH Legal and get back to us with a response.

19) At the last Quarterly Meeting, we raised the issue of employees being able to get a copy of their interview form during a survey interview. In the past, IDPH refused to give a copy of the interview form to the employee. We argued this strongly and they stated they would discuss internally and get back to us. At this meeting, IDPH stated they will now give a copy of the interview form to the employee (not the facility) if they request it. They also stated that the past practice of giving blank interview forms to employees to sign will also stop. Also, with respect to employee interviews, employees can request a witness during an interview.
and IDPH cannot deny that request. The witness is of the employee’s choice, not the facility’s. The witness is just that, a witness, and cannot be involved in the interview process.

IDPH promised several emails on some of the issues above and we will forward them to our members as soon as we receive them.

**CMS’s Announcement of Calendar Year 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter**

On April 4, 2016, the CMS published the Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. This document updates Medicare Advantage (MA) and Part D plan payment rates and sets forth policy changes that will determine how MA and Part D plans are regulated in 2017. The Announcement finalizes several payment and policy changes proposed in the 2017 Advance Notice and Draft Call Letter for MA and Part D plans, and addresses stakeholder comments submitted in response to CMS’s proposals. For additional information, please refer to AHCA’s summary of the 2017 Advance Notice and Draft Call Letter and comments submitted on those provisions most pertinent to SNFs.

Highlights of the 2017 Announcement and Final Call Letter include:

- Payment rates for MA plans will increase by 0.85 percent on average for 2017, according to the Announcement, which is lower than the 1.35 percent increase estimated in the Advance Notice. CMS noted that the change is a result of a technical update in the "risk adjustment normalization factor," which is intended to better reflect historical population trends to improve the accuracy of risk adjustment. When factoring in MA coding trends, the MA plans are expected to experience an average increase of 3.05 percent.

- In 2016, CMS initiated the transition to encounter data based risk scores by blending risk scores from the Risk Adjustment Processing System (RAPS)/FFS and the Encounter Data System (EDS), using weights of 90 percent and 10 percent, respectively. In the Advance Notice, CMS proposed increasing the weight of the EDS risk score to 50 percent for 2017. However, in response to stakeholder feedback, CMS will use a lower percentage of EDS risk scores than was proposed in the Advance Notice. Specifically, risk scores will be calculated using weights of 25 percent EDS risk scores and 75 percent RAPS/FFS risk scores. CMS also states its intent to fully phase-in the use of encounter data for risk score calculations by 2020.

- CMS has long indicated that statistical evidence shows that there may be a causal relationship between the dual-eligible and/or disability status of an MA plan’s enrollees and that plan’s ability to achieve high ratings on certain Star Ratings measures. While CMS states that additional research is needed to identify a long term solution, CMS finalized its proposal from the Advance Notice to implement an interim analytical adjustment to Star Ratings to account for dual-eligible and/or disability status.

- The Affordable Care Act (ACA) placed a mandatory maximum annual limit on all out-of-pocket medical costs for MA plans, which is referred to as the Maximum Out of Pocket (MOOP). MA plans may also elect a lower voluntary MOOP in exchange for increased flexibility in establishing cost sharing amounts for individual service categories. In the Final Call Letter, CMS finalized its proposal to reduce the cost sharing limit for voluntary MOOP plans for SNF days 1-20 from $40 per day to $0 per day for CY 2018 MA plans so that SNF cost sharing will align with Original Medicare for both voluntary and mandatory MOOP.

AHCA/IHCA will review the Final Announcement and Call Letter in its entirety and will keep you informed of any key changes from CMS’s initial proposals that may impact SNFs. AHCA/IHCA will continue to monitor any developments and will keep you apprised of any additional announcements.
Patient Safety in the Nursing Home Setting

National Healthcare Quality and Disparities Report

This Patient Safety Chartbook (click here) is part of a family of documents and tools that support the National Healthcare Quality and Disparities Reports (QDR). The QDR are annual reports to Congress mandated in the Healthcare Research and Quality Act of 1999 (P.L. 106-129). These reports provide a comprehensive overview of the quality of health care received by the general U.S. population and disparities in care experienced by different racial, ethnic and socioeconomic groups. The purpose of the reports is to assess the performance of our health system and to identify areas of strengths and weaknesses in the health care system along three main axes: access to health care, quality of health care and priorities of the National Quality Strategy.

More than 3 million people receive care in U.S. nursing homes and skilled nursing facilities each year (CDC, 2015).

For nursing home residents, optimal care seeks to maximize quality of life and minimize unintended complications.

Measures tracked for patients of various age ranges include:
- Nursing home residents with urinary tract infections.
- Nursing home residents experiencing use of restraints.
- Nursing home residents who have pressure ulcers.
- Nursing home residents who had a fall with major injury.
- Nursing home residents who received antipsychotic medication.

Urinary Tract Infections

Long-stay nursing home residents experiencing urinary tract infections, by sex and race/ethnicity, 2011-2013

2011 Achievable Benchmark: 6.1 percent.

Source: Centers for Medicare & Medicaid Services, Minimum Data Set, 2011-2013.

Denominator: Nursing home residents of any age who have at least 101 cumulative days in the facility.

Note: For this measure, lower percentages are better. The measure was calculated as follows: Percentage of long-stay residents with a urinary tract infection within the 30 days prior to assessment. White, Black, and Asian are non-Hispanic. Hispanic includes all races.

- Importance: Bacteria that cause urinary tract infections (UTIs) can spread to other body parts and become more serious or contribute to further complications, such as delirium.
• **Overall Percentage:** In 2013, the percentage of long-stay nursing home residents with a UTI was 6.4 percent.

• **Groups With Disparities:**
  o In 2013, compared with males (5.1 percent), the percentage with UTIs was worse for females (7 percent).
  o In 2013, compared with White residents (6.8 percent), the percentage of residents with UTIs was lower for Blacks and Asians (4.7 percent), as well as Hispanics (5.4 percent).

• **Achievable Benchmark:**
  o In 2011, the top 5 State achievable benchmark for UTIs was 6.1 percent. The States that contributed to the achievable benchmark are Connecticut, Hawaii, Minnesota, North Dakota, and Pennsylvania.
  o Males, Blacks, Asians, and Hispanics have achieved the benchmark.

### Use of Restraints

Long-stay nursing home residents experiencing use of restraints, by sex and race/ethnicity, 2011-2013

Left Chart:

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<td>1.9</td>
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<td>75-84</td>
<td>2.61</td>
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<tr>
<td>85+</td>
<td>2.46</td>
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Right Chart:

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<td>2.46</td>
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</tbody>
</table>

2011 Achievable Benchmark: 0.7 percent.

**Source:** Centers for Medicare & Medicaid Services, Minimum Data Set, 2011-2013.

**Denominator:** Nursing home residents of any age who have at least 101 cumulative days in the facility.

**Note:** For this measure, lower percentages are better. The measure was calculated as follows: Percentage of long-stay residents who are physically restrained on a daily basis.

• **Importance:** Residents who are restrained daily can become weak, lose their ability to go to the bathroom by themselves, and develop pressure ulcers or other medical conditions.

• **Overall Percentage:** In 2013, the percentage of long-stay nursing home residents who were physically restrained on a daily basis was 1.4 percent.

• **Groups With Disparities:**
  o In 2011, 2012, and 2013, the percentage of residents with restraint use on a daily basis was lower for those ages 65-74 years compared with those under age 65. In 2013, the percentage of residents ages 65-74 years experiencing use of restraints was 1.2 percent compared with 1.6 percent for residents younger than 65.
  o In 2013, compared with Whites (1.4 percent), Asians (2 percent) and Hispanics (1.8 percent) had worse percentages of daily restraint use and Blacks (1.2 percent) had a better percentage of daily restraint use.

• **Achievable Benchmark:**
  o In 2011, the top 5 State achievable benchmark for restraint use was 0.7 percent. The States that contributed to the achievable benchmark are Kansas, Maine, Nebraska, New Hampshire, and Vermont.
  o No group achieved the benchmark from 2011 to 2013.
Pressure Ulcers
Long-stay nursing home residents who have pressure ulcers, by sex and race/ethnicity, 2011-2013

2011 Achievable Benchmark: 0.7 percent.
**Source:** Centers for Medicare & Medicaid Services, Minimum Data Set, 2011-2013.
**Denominator:** Nursing home residents of any age who have at least 101 cumulative days in the facility.
**Note:** For this measure, lower percentages are better. The measure was calculated as follows: Percentage of long-stay residents who are physically restrained on a daily basis.

- **Importance:** Pressure ulcers are serious medical conditions. They typically result from prolonged periods of uninterrupted pressure on the skin, soft tissue, muscle, and bone. Vulnerable patients include older adults; stroke and diabetic patients; patients with dementia, circulatory diseases, dehydration, and malnutrition; and people who use wheelchairs or are bedridden—that is, any patient with impaired mobility or sensation.
- **Overall Percentage:** In 2013, the percentage of low-risk short-stay residents with pressure ulcers was 1.3 percent and the percentage of high-risk long-stay residents with pressure ulcers was 7.7 percent.
- **Groups with Disparities:**
  - As in 2011 and 2012, male low-risk short-stay nursing home residents had a worse percentage with pressure ulcers (1.5 percent) compared with female residents (1.2 percent) in 2013.
  - As in 2011 and 2012, male high-risk long-stay nursing home residents had a worse percentage with pressure ulcers (9.4 percent) compared with female residents (7.0 percent) in 2013.
- **Achievable Benchmark:**
  - The 2011 top 5 State achievable benchmark for low-risk short-stay nursing home residents was 1.0 percent. The States that contributed to the benchmark were Alabama, Arizona, Colorado, Connecticut, and Idaho.
  - The 2008 top 5 State achievable benchmark for high-risk long-stay nursing home residents was 7.1 percent. The States that contributed to the benchmark were Hawaii, Minnesota, Nebraska, New Hampshire, and North Dakota.
  - No low-risk short-stay residents achieved the benchmark from 2011 to 2013. Among high-risk long-stay residents, only females achieved the benchmark by 2013.
Antipsychotic Medication Among Residents With Dementia

Long-stay nursing home residents with dementia who received antipsychotic medication, by sex and race/ethnicity, 2012-2013

2012 Achievable Benchmark: 15.0 percent.

Key: NHOPI = Native Hawaiian or Other Pacific Islander; AI/AN = American Indian or Alaska Native.

Source: Centers for Medicare & Medicaid Services, Minimum Data Set, 2012-2013.

Denominator: Nursing home residents of any age who have at least 101 cumulative days in the facility, who are 18 years and over with a diagnosis of Alzheimer’s disease or non-Alzheimer’s dementia, excluding residents with schizophrenia, Tourette’s syndrome, and Huntington’s disease.

Numerator: Use of an antipsychotic medication verified in Section N (N0410A) greater than or equal to 12 days.

Note: For this measure, lower percentages are better.

- **Importance**: The high use of antipsychotic medications among nursing home residents for indications other than those for which the drug was approved has been noted by the Federal Government. These drugs are often used for too long, at too high a dose, or when unnecessary. In the past, inappropriate prescribing of antipsychotics in nursing homes has primarily been considered a marker of suboptimal care. Recent studies have shown antipsychotic use is also a drug safety issue (Huybrechts, et al., 2012). Antipsychotic medication use is associated with increased risks of adverse events such as movement disorders, falls, hip fractures, and cerebrovascular events. Their use in older adults with dementia carries an increased risk of death. Safety concerns with antipsychotic medication use in older adults also include the risks of hyperprolactinemia, pneumonia, thromboembolism, cerebrovascular events, and other cardiovascular adverse events (Chiu, et al., 2015).

- **Overall Percentage**: The percentage of long-stay nursing home residents who had antipsychotic medications was 17.6 percent in 2013.

- **Groups With Disparities**:
  - In 2013, the percentage of residents receiving antipsychotic medication was higher for Hispanic residents (20.1 percent) than for White residents (18.0 percent).
  - In 2012 and 2013, the percentage of long-stay residents who received antipsychotic medications was worse for residents with one or more chronic conditions than for residents with no chronic conditions.

- **Achievable Benchmark**:
  - The 2012 top 6 State achievable benchmark was 15.0 percent. The States that contributed to the achievable benchmark are Alaska, California, Hawaii, Michigan, New Jersey, and Wyoming.
  - Asians, NHOPIs, residents with no chronic conditions, and residents with one chronic condition achieved the benchmark.
Antipsychotic Medication Among Residents With Dementia, by State

Long-stay nursing home residents who received antipsychotic medication, by state, 2013

![Map of the United States showing antipsychotic medication usage by state.](image)

**Source:** Centers for Medicare & Medicaid Services, Minimum Data Set, 2013.

**Denominator:** Nursing home residents of any age who have at least 101 cumulative days in the facility.

**Note:** For this measure, lower percentages are better.

- **Overall:** This map shows overall rankings of States (by quartiles) in the percentage of long-stay nursing home residents who received antipsychotic medication in 2013. Values ranged from 8.5 percent to 23.4 percent.

- **Differences by State:** Interquartile ranges follow:
  - First quartile (lowest): 8.5 percent-15.3 percent (AK, CA, DC, DE, HI, MD, MI, MN, NJ, NC, SC, WI, WV).
  - Second quartile (second lowest): 15.3 percent -17.3 percent (CO, ID, MT, NM, NY, ND, OR, PA, RI, SD, VT, WA, WY).
  - Third quartile (second highest): 17.4 percent-19.2 percent (AZ, CT, GA, IN, IA, KS, ME, MA, MO, NV, OH, OK, VA).
  - Fourth quartile (highest): 19.3 percent-23.4 percent (AL, AR, FL, IL, KY, LA, MS, NE, NH, TN, TX, UT).
  - Eight of the 12 States in the quartile with the highest percentage of long-stay nursing home residents who received antipsychotic medication were in the South.

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**Important Regulations, Notices & News Items of Interest**

1) **RN Licensing:** or those RNs out there, remember that your licenses are due for renewal by **May 31, 2016.** The state is not sending notices anymore, so you’ll need to renew on your own through IDFPR. They recently announced implementation of electronic renewals for professions licensed and regulated by the Divisions of Real Estate and Professional Regulation. License renewals can be completed online via the agency website [click here](#). Proof of licensure can be found at the License Lookup page. And if you want to be reminded electronically, just visit the online address change site to provide a current email address and contact information.
2) The following federal Survey and Certification (S&C) Letters were released since the last issue of *Regulatory Beat*:

- **S&C 16-18 – CLIA** – Personnel Policies for Individuals Directing or Performing Non-waived Tests. This policy memorandum supersedes S&C-10-07-CLIA “Consolidation of Personnel Policies for Individuals Directing or Performing Non-waived Tests under the Clinical Laboratory Improvement Amendments (CLIA).” CLIA surveyors will now accept Primary Source Verification (PSV) as evidence of compliance with the personnel qualifications mandated in Subpart M of the Clinical CLIA Regulations. If there are required elements in the personnel regulations that the PSV company does not verify, it is the laboratory director’s (LD) responsibility to ensure that these personnel qualifications are met by other means. CLIA personnel regulations and the policy on mandatory citations are not changing. Laboratories may choose to submit primary source verification for LD qualifications. Bachelor’s and Associate’s degrees in nursing meet the requirement for earning a degree in a biological science for, respectively, high complexity testing personnel and moderate complexity testing personnel.

- **S&C 16-19 – All** - Computed Tomography (CT) Compliance Clarifications under Section 218(a)(1) of the Protecting Access to Medicare Act (PAMA)- Information Only. CMS is sharing this clarification with State and Federal Surveyors as information only. Surveyors will not be expected to determine compliance with Advanced Diagnostic Imaging (ADI) requirements. CMS is providing compliance and payment clarifications based on stakeholder questions regarding National Electrical Manufacturers Association (NEMA) XR-29 Standard. Frequently Asked Questions (FAQs) attached with this policy memorandum aim to clarify stakeholder uncertainty and to include aspects of payment reductions if CT systems are found non-compliant.

- **S&C 16-20 – CLIA** - Policy Clarification on Acceptable Control Materials Used when Quality Control (QC) is Performed in Laboratories. CMS is providing clarification regarding the policy on acceptable control materials, including the following: Acceptable control materials - will now include on-board controls, i.e. ampules or cartridges containing the same QC material that would traditionally be considered as external QC. Function checks and procedural controls - Instrument/electronic function checks and procedural controls do not fulfill the regulatory requirement for control materials. Guidance for surveyors - The laboratory Director is responsible for the determination of what control materials to use in his/her laboratory. Surveyors will ensure that the laboratory is following its own established policies, specifically its QC procedures, in the context of the Outcome Oriented Survey Process.

3) Federal HHS/CMS released the following notices/announcements since the last issue of *Regulatory Beat*:

- On April 1, CMS announced that the Comprehensive Care for Joint Replacement Model (CJR) was launched. It is a major step toward transforming care delivery in Medicare because the model looks to improve care and quality for the most common procedures that Medicare beneficiaries have, hip and knee replacements. About 800 hospitals located in 67 selected markets will be accountable for the costs and quality of related care from the time of the surgery through a post-hospitalization period. Hospitals will receive a target price at the beginning of the year. Hospitals where quality of care is high and spending is less than the target may receive additional payment from Medicare. Hospitals where spending is above the target may be required to repay Medicare for a portion of the difference. Beneficiaries will continue to choose their doctor, the hospital where they receive treatment, and the type and location of rehabilitation care they receive. If their hospital is a model participant, they will get a letter explaining the model. Patients whose chosen hospital participates in the model should experience improved care coordination. For instance, it is expected that nursing facilities will understand a patient’s needs better before that patient is discharged from the hospital. A notice about the launch can be found [here](#).

- **National Partnership to Improve Dementia Care and QAPI Call** — Registration Now Open - Thursday, April 28 from 1:30 to 3 pm ET. To Register: Visit [MLN Connects Event Registration](#). Space may be limited, register early. This call focuses on infection control, highlighting Antibiotic Stewardship and community-wide efforts,
including a presentation from a nursing home administrator. Common concerns related to the clash between individualized, person-centered care and the medical model of controlling infections will also be addressed. This is critical for residents with dementia, who often struggle to complete complex tasks and may have issues with continence. Additionally, CMS subject matter experts will share information about the upcoming Infection Control Pilot Project, as well as updates on the progress of the National Partnership to Improve Dementia Care in Nursing Homes and Quality Assurance and Performance Improvement (QAPI). A question and answer session will follow the presentations.

- **ACOs: What Providers Need to Know Fact Sheet — Revised.** A revised Accountable Care Organizations: What Providers Need to Know Fact Sheet is available. Learn about: Participating in the Medicare Shared Savings Program; Coordinating care through Accountable Care Organizations (ACOs); Satisfying the quality performance standards.

- **Improving Quality of Care for Medicare Patients: ACOs Fact Sheet — Revised.** A revised Improving Quality of Care for Medicare Patients: Accountable Care Organizations (ACOs) Fact Sheet is available. Learn about: The 34 measures of quality performance; Reporting clinical quality measures; Incorporating the Physician Quality Reporting System and Value-Based Payment Modifier in the Medicare Shared Savings Program.

- **Learn about the SNF Value-Based Purchasing Program at Open Door Forum - Thursday, April 28 from 2 to 3 p.m. ET.** The next Skilled Nursing Facility (SNF)/Long-Term Care Open Door Forum is rescheduled for Thursday, April 28. Learn about the SNF Value-Based Purchasing Program, which will begin in FY 2019. For questions, contact SNFVBPinquiries@cms.hhs.gov.

- **Medicare Quarterly Provider Compliance Newsletter Educational Tool — New.** A new Medicare Quarterly Provider Compliance Newsletter [Volume 6, Issue 3] Educational Tool is available. Learn about: How to avoid common billing errors and other erroneous activities when dealing with the Medicare Program; How to address and avoid the top issues this quarter.


4) Recent investigations by the Office of Inspector General have shown a number of instances in which hospices inappropriately billed Medicare for hospice general inpatient care (GIP). Misuse of GIP includes care being billed but not provided and beneficiaries receiving care they do not need. Such misuse has human costs for this vulnerable population as well as financial costs for Medicare. The goals of hospice care are to help terminally ill beneficiaries with a life expectancy of 6 months or less to continue life with minimal disruptions and to support beneficiaries' families and other caregivers. The care is palliative, rather than curative. Hospices must establish an individualized plan of care for each beneficiary. GIP is the second most expensive level of hospice care and is intended to be short-term inpatient care for symptom management and pain control that cannot be handled in other settings.

5) The Agency for Healthcare Research and Quality (AHRQ) is hosting a webinar on April 13, 2016 from 1 to 2 p.m. ET on the implementation of TeamSTEPPS® across multiple settings. The webinar, "Using TeamSTEPPS to Reduce Patient Harm: Strategies and Successes across Multiple Settings," will feature Bill Laxton, RN, BSN, CPHRM, director of the Risk and Patient Safety Department in the Clinical Services Group at the Healthcare Corporation of America (HCA). His presentation will include HCA's history with TeamSTEPPS; lessons learned from over seven years of implementation and sustainment; and specific successes related to the reduction of patient harm. Specifically, the presentation will seek to:

1. Provide an overview of HCA's work with TeamSTEPPS across multiple facilities and settings;
2. Discuss some lessons learned through both successes and failures, and;
3. Discuss the implementation of and results associated with specific TeamSTEPPS interventions that have been linked to reductions in patient harm in areas such as falls and retained foreign bodies.

There is no cost to participate. Click here to register.

6) The Illinois Department of Healthcare and Family Services (HFS) announced that effective with inpatient discharges on and after January 1, 2016, the Department updated to APR-DRG version 33 and the corresponding HAC utility software which utilizes the HAC codes defined by CMS. The Department’s HAC webpage provides a link to the current CMS HAC list.

7) The American Health Care Association (AHCA) provided IHCA two notices of interest:

   • The Medicare Payment Advisory Commission (MedPAC) unanimously approved a conceptual model for a unified cross-setting post-acute care (U-PAC) payment system. The prototype U-PAC proposal will be submitted to Congress in June. The MedPAC report is the first of three PAC payment reform reports statutorily mandated by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The initial MedPAC report is intended to lay the foundation for more detailed DHHS work on the development of a unified PAC, cross-setting payment system. In follow up to the report, the U.S. Department of Health and Human Services (DHHS) is required respond to the June 2016 MedPAC document by 2020. A final proposal for a U-PAC payment system is due to Congress no later than 2023. Of note, the June 2016 report is not binding in any way. Congress and DHHS may or may not adopt or act upon, respectively, the contents of the report. Considerable further research and policy development is needed before delivery of a final U-PAC proposal.

   • AHCA has just released its latest FAQ document regarding the mandatory Electronic Staffing Data Collection in early April. The document includes answers to common questions from members about the payroll based journal. For questions, please contact us via our dedicated email address. All of the materials including the webinar, handouts and other useful resources can be found online through ahcancaEd (click here). To view all of the materials be sure to log in and then register for the product.

8) The latest Telligen events/announcements can be found at https://www.telligenqinqio.com/.

9) MedlinePlus recently published three interesting articles:

   • Is Seniors’ Dental Health Tied to Mental Health? There seems to be a link between poor oral health and age-related mental decline, researchers say. However, the researchers emphasized there is not enough evidence to prove a direct link between oral health and thinking ("cognitive") abilities. In a new report, investigators reviewed studies on oral health and cognition published between 1993 and 2013. Some of the studies found that oral health indicators -- such as the number of teeth, the number of cavities and the presence of gum disease -- was associated with a higher risk of mental decline or dementia, while other studies did not find any association.

   • Cost of Insulin Rises Threefold in Just a Decade. Americans with diabetes who rely on insulin to keep their blood sugar levels in check are facing sticker shock: A new study finds the price of insulin has tripled in only 10 years. Moreover, since 2010, per-person spending on insulin in the United States was more than spending on all other diabetes drugs, the study found.

   • Severe Depression Linked to Dementia in Seniors. Major and worsening depression may significantly increase seniors’ risk of dementia, a new study suggests. The research included close to 2,500 people in their 70s who did not have any signs of dementia at the start of the study. The participants were monitored for five years for symptoms of depression, and then for six years for signs of dementia. Dementia developed in just over 21 percent of participants with serious and escalating symptoms of depression, compared to about 12 percent
of those with consistently minimal symptoms of depression, the findings showed.

10) **AARP:** Price hikes doubled average drug price over 7 years. The average cost for a year's supply of a prescription drug doubled in just seven years to more than $11,000 — about three-quarters of the average annual Social Security benefit. That's according to the latest study of price trends for widely-used drugs conducted by AARP, the senior citizens advocacy group. It finds prices for existing drugs, driven entirely by manufacturer price hikes, have been rising more quickly since 2007 and likely will continue to do so. AARP says its research shows drugmaker price hikes imposed one or more times a year are making prescription medicines increasingly unaffordable for retirees and many other patients. That's particularly true for people taking multiple drugs or needing long term medication for chronic health problems, not to mention the uninsured. An August poll by the Kaiser Family Foundation found 24 percent of Americans were having trouble paying for their medicines. That rose to 43 percent for those in poor health.

11) **Medscape** recently published several articles of interest:

- **USPSTF: Final Guidelines on Aspirin as CVD, Cancer Prevention.** People aged 50 to 69 years who have a 10 percent or greater 10-year risk for cardiovascular disease (CVD) and who do not have higher risk for bleeding should consider taking low-dose aspirin to help prevent CVD and colorectal cancer, according to final recommendations from the US Preventive Services Task Force (USPSTF). Full recommendation and evidence reviews were published online April 12 in the *Annals of Internal Medicine.* Medscape Medical News previously reported on the draft recommendations issued in September. People considering starting an aspirin regimen should have a life expectancy of at least 10 years and be willing to take the low-dose aspirin (≤100 mg/day) for at least 10 years, according to the guidance, written by Albert L. Siu, MD, MSPH, on behalf of the task force.

- **HHS Releases National Pain Strategy.** A National Pain Strategy that outlines the federal government's first coordinated plan for reducing the burden of chronic pain has been released. The report, issued by the Office of the Assistant Secretary for Health at the Department of Health and Human Services (HHS), comes on the heels of new opioid prescribing guidelines released recently by the Centers for Disease Control and Prevention (CDC).

- **Type 2 Diabetes Rates Quadruple Worldwide Since 1980.** The number of adults with diabetes has reached almost 450 million worldwide, and low- and middle-income countries have experienced the fastest increases, according to new calculations released to coincide with the WHO's World Health Day on April 7, for which the theme this year is "Beat Diabetes." "[Since 1980, age-standardized diabetes prevalence] more than doubled in men and increased by 60 percent in women worldwide....This rise in prevalence has been compounded by population growth and aging, nearly quadrupling the number of adults with diabetes over these 35 years," write Majid Ezzati, PhD, from Imperial College London, United Kingdom, and colleagues, all with the NCD Risk Factor Collaboration (NCD-RisC), in their paper published online April 6 in the *Lancet.*

12) **Medical News Today** recently published two articles of interest:

- **New Antibiotic Stewardship Guidelines Focus on Practical Advice for Implementation.** Preauthorization of broad-spectrum antibiotics and prospective review after two or three days of treatment should form the cornerstone of antibiotic stewardship programs to ensure the right drug is prescribed at the right time for the right diagnosis. These are among the numerous recommendations included in new guidelines released by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) and published in the journal *Clinical Infectious Diseases.*

- **Six-Step Hand-Washing Technique Found Most Effective For Reducing Bacteria – Study Compares CDC’s 3-Step Hand Hygiene with WHO’s 6-Step Process.** New research demonstrates that the six-step hand-hygiene technique recommended by the World Health Organization is superior to a three-step method suggested by the U.S. Centers for Disease Control and Prevention (CDC) in reducing bacteria on healthcare workers' hands. The study was published online in *Infection Control and Hospital Epidemiology,* the journal of the Society for Healthcare Epidemiology of America.
13) **Infection Control Today** reports that Coordinated Response Could Reduce Spread of Emerging Superbug in Healthcare Facilities. A simulation of how the so-called superbug carbapenem-resistant Enterobacteriaceae (CRE) might spread among health care facilities found that coordinated efforts prevented more than 75 percent of the often-severe infections that would have otherwise occurred over a five-year period. The study was led by researchers at the Johns Hopkins Bloomberg School of Public Health and published last month in the American Journal of Epidemiology.

14) **EurekAlert** published an article entitled, “Why Do People With Alzheimer’s Stop Recognizing Their Loved Ones?” Alzheimer's not only steals people’s memories but also their ability to recognize faces, which widens the gulf between people with this disease and their loved ones. A recent study has demonstrated that, beyond causing memory problems, Alzheimer’s disease also impairs visual face perception. This finding may help families better understand their loved one's inevitable difficulties and lead to new avenues to postpone this painful aspect of the disease. Research in this area by the team of Dr. Sven Joubert, PhD, a researcher at the Centre de recherche de l’Institut universitaire de gériatrie de Montréal and a professor with the Department of Psychology at Université de Montréal, will be published in the *Journal of Alzheimer's Disease*.

15) **McKnight**’s had several articles of interest:

- **Hospital Readmission Penalties for SNFs Pose ‘Critical Problems’**. A provision of the Protecting Access to Medicare Act that will penalize both the skilled nursing facility and hospital for rehospitalizations will require SNFs to address some “critical problems,” according to a new report. The rehospitalization provision, set to go into effect in 2018, would hold both hospitals and SNFs responsible for any patient that returns to the hospital within 30 days of discharge. While that set-up is beneficial to patients, it poses a new set of risks for SNF operators, said Jennifer Carnahan, M.D., MPH, of the Indiana University Center for Aging Research. Carnahan, along with other researchers from Indiana University and the Regenstrief Institute contributed to “Hospital Readmission Penalties: Coming Soon to a Nursing Home Near You,” published in the March issue of the *Journal of the American Geriatrics Society*.

- **End-Of-Life Discussions in Nursing Homes Improve Outcomes, Reduce Odds of Dying in Hospital**. A relatively low number of nursing home residents participate in end-of-life discussions, despite the potential they have to improve outcomes, according to a study in the March issue of *Age and Ageing*. The end-of-life discussions tracked by the researchers included talks about the course and prognosis of a resident's disease, the approaching end of life, the possibility of stopping treatments, options for palliative care, psychological issues, and spiritual or existential problems. In their last months of life, residents who discussed three or more end-of-life topics with physicians were less likely to die in a hospital, more likely to appoint a surrogate or representative and more likely to choose to withdraw life-prolonging medical treatments, researchers found. Those results highlight the need for nursing home physicians to have end-of-life conversations with residents, researchers said, although those conversations may be challenging to initiate with very old residents, or those with dementia.

- **Long Term Care Residents With Dementia Often Over-Prescribed Drugs**. Residents of long term care facilities with dementia are often overprescribed drugs that can cancel out the effects of their dementia medications, according to a new study. Researchers at the University of Toronto and Toronto’s Institute for Clinical Evaluative Sciences analyzed data from seniors living in long term care facilities, as well as community-dwelling seniors, to explore the link between seniors taking both cholinesterase inhibitors for dementia and drugs with anticholinergic effects. The study also looked at the association between seniors’ drug burdens — the cumulative effect of using multiple anticholinergic drugs — and the number of physicians they see each year. Full results of the study were published online late last month, as part of the March issue of the *Journal of the American Geriatrics Society*. Results showed that 60 percent of long term care residents with dementia were taking cholinesterase inhibitors along with anticholinergic drugs, which are commonly prescribed for ailments like depression, sleep problems and incontinence. Those medications have been shown to cause cognitive impairment and confusion. The study also showed that residents who saw multiple physicians over
the course of a year had increased drug burdens and risk of drug interactions. On average, long term care
residents saw an average of 10 different physicians, researchers found.

- **Five-Star, Consumer Rankings Agree ‘Minimally’ on SNF Quality.** Current government ratings for nursing
  homes such as Nursing Home Compare differ so much from consumers' personal rankings, they could benefit
  from personalization, according to a [new study](https://www.longevitymedicine.com/news/five-star-consumer-
  rankings-agree-minimally-on-snf-quality/). Conducted by researchers at the University of California-Irvine,
  the study targeted government-provided, Five-Star Ratings System-based nursing home ratings, like those
  found on the CMS's Nursing Home Compare website. Nursing Home Compare offers a “one-size-fits-all-
  patients” look at skilled nursing facilities that doesn't take into account individual patients' medical needs
  and preferences, researchers said. Allowing consumers to personalize the nursing home ratings could paint
  a broader picture of the facilities, and help consumers choose which provider is the best for them, the team
  suggested.

- **Managed Care Will Hit SNFs Relying on Part A Payments.** Skilled nursing providers should be prepared for
  managed care to drill down on Medicare Part A residents, creating the potential for major financial problems,
  a long term care expert warned recently. Managed care experts “don't see what value we add to the
  equation — you need to prove it,” said Jill M. Krueger, the president and CEO of Symbria in Warrenville, IL,
  during a session at the LeadingAge Illinois annual meeting. “The pendulum is going to swing and they'll drill
  down on Medicare rates. Then you'll show the data and it will swing back, but there will be a 3-year period
  where you need money in your piggy banks as money from Part A moves to managed care.” In states where
  there is more managed care, the length of stay is as low as 14 days, said Krueger, speaking at a session titled
  “Contracting with ACOs and Other Multi-Provider Arrangements” with attorney and McKnight's Ask the Legal
  Expert columnist John Durso. In addition to a loss of census around a short length of stay, more patients are
  bypassing skilled nursing for home health and SNFs can be excluded from narrow networks in ACOs.
  Providers — especially in the nonprofit sector — should recognize the importance of relationship building.

- **Potentially Fatal Drug Errors Missed by Electronic Ordering Systems.** Computerized physician order entry
  systems don't always catch potentially harmful or fatal medication errors, according to a [report released
  recently](https://www rencont.com/news/health/2015/05/18/computerized-physician-order-entry-systems-
  don-t-catch-potentially-harmful-or-fatal-medication-errors). Tests conducted by the Leapfrog Group, a nonprofit
  organization that reports on hospital safety, found that hospitals' CPOE systems didn't flag 39 percent of potentially
  harmful drug orders. The systems also missed 13 percent of potentially fatal orders, the report found. The most common
  errors that went undetected by the system include prescribing patients the wrong drug, requested an incorrect
  dosage of a drug or incidents where follow-up reminders failed to appear. Despite the unflagged errors, hospitals'
  ability to detect potential drug errors has actually improved slightly since 2014, the report found.

- **Nursing Home Compare Hurt by Mistrust and Unawareness.** Consumers react positively to Nursing Home
  Compare, but they limit use based on lack of awareness and initial lack of trust in the data, according to a
  new analysis. The government website gives details and ratings about the nation's nursing homes. The
  report, which appears in April's *Health Affairs* under the title “Use Of Nursing Home Compare Website
  Appears Limited By Lack Of Awareness And Initial Mistrust Of The Data,” examines whether consumers are
  using the rating system in choosing nursing home placement. “Our findings suggest that efforts to expand the
  use of Nursing Home Compare should focus on awareness and trust,” report authors R. Tamara Konetzka,
  Ph.D., and Marcelo Coca Perraillon wrote. “Useful additions to Nursing Home Compare might include
  measures of the availability of activities, information about cost, and consumer satisfaction.”

- **CMS's Quality Improvement Program Made Antipsychotic Reduction, Drug Safety Strides in 2015.** CMS's
  Quality Innovation Networks showed significant success in reducing antipsychotic use, bolstering medication
  safety and improving care transitions in nursing homes, according to a 2015 progress report. States covered
  by two of the QINs – programs designed to enhance the quality of services for Medicare beneficiaries — have
  achieved “large-scale” antipsychotic medication reductions through pilot efforts.
OIG to Tackle Adverse Events, Therapy Payments in Nursing Homes, Federal regulators' investigative arm has set its sight on adverse events in nursing homes, and how Medicare pays for skilled nursing therapy, according to a report released Tuesday. The Office of Inspector General's 2016 Compendium of Unimplemented Recommendations outlines 25 unimplemented recommendations the office says would help cut costs and improve quality among Department of Health & Human Services programs. Many of the office's recommendations have seen some progress, but as of the publishing date, OIG believed “more should be achieved,” report authors stated. Included in the report is OIG's recommendation that the CMS increase its efforts to identify and prevent adverse events, including substandard treatment, inadequate resident monitoring, or failure to provide necessary care. CMS, along with the Agency for Healthcare Research and Quality, concurred with OIG's recommendation.

16) **Interesting Fact:** For the first time in human history, overweight people outnumber underweight people in the U.S.