Issues to Watch
Overview of Hot Topics in Health Care Compliance

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The Queen’s Health Systems

- The Queen’s Medical Center
  - Level 1 Trauma Center located in downtown Honolulu
  - emergency admissions 3,181
  - ER visits 56,013
  - OP visits 134,011

- The Queen’s Medical Center - West O’ahu
  - Community hospital located in Ewa
  - 68 acute beds
  - emergency admissions 1,597
  - ER visits 25,282
  - OP visits 41,318

- Molokai General Hospital
  - Critical Access Hospital located in Kaunakakai on Molokai
  - 15 bed rural health care facility
  - emergency admissions 49
  - ER visits 2,226
  - OP visits 7,226

- North Hawai’i Community Hospital
  - Rural acute care in Waimea on Hawai’i
  - 25 acute beds
  - emergency admissions 45
  - ER visits 2,133
  - OP visits 5,322

- Queen’s Development Corporation
  - Manages Queen’s Health Care Centers with campuses on Oahu, Big Island and Maui
  - POBs, OP, pharmacies, & parking

- Queen’s Insurance Exchange, Inc.
  - Provides liability insurance coverage for QHS and affiliates

- Queen’s Clinically Integrated Physician Network
  - Physician led network transforming health care by developing and adopting clinical best practices

- Queen’s MSSP ACO, LLC
  - Medicare shared savings program created to encourage health care providers and entities to work together to improve patient health and reduce unnecessary costs of care
Objectives

"Rapid fire" overview of hot topics that keep showing up with regulators and within the enforcement community

Agenda

• New Types of MAC Reviews
• Telemedicine and upcoming changes
• Continued scrutiny of device credits
• Provider-Based location challenges
• 340B program changes
• More appearances of Shared Decision Making
• And Others!

NEW TYPES OF MAC REVIEWS
Targeted Probe & Educate (TP&E)

**HOW DOES IT WORK?**

If chosen for the program, you will receive a letter from your Medicare Administrative Contractor (MAC). You will be given at least a 45-day period to make changes and improve. If some claims are denied, you will be invited to a one-on-one education session. The MAC will review 20-40 of your claims and supporting medical records. If compliant, you will not be reviewed again for at least 1 year on the selected topic.*

*MACs may conduct additional review if significant changes in provider billing are detected.

**Select Topics/Providers for Targeted Review Based Upon Data Analysis**

**Probe 20-40 Claims Per Provider/Supplier**
- Compliant? Educate – Can Occur Intra-Probe
- Allow ≥ 45 Days (so provider has time to improve)

**Probe 20-40 Claims Per Provider/Supplier**
- Compliant? Improve – Provider Compliant?
  - Order to Discontinue for at least 12 months

**What are some common claim errors?**
- Missing or incomplete orders or certifications/recertification
- Expired orders or certifications/recertifications
- Signature missing on order, certification/recertification, encounter note
- Documentation does not meet medical necessity (NCD, LCD, Conditions of Payment)

**What if there is no improvement?**
CMS has reported that the majority of those that have participated in the TPE process increased the accuracy of their claims. However, failure to improve after 3 rounds of TPE will be referred to CMS for next steps.
Provider Billing Analysis Letters (PBAL)

**BASED ON DATA ANALYTICS**

**EDUCATIONAL IN NATURE**

Noridian Healthcare Solutions, LLC (Noridian) is the Jurisdiction E (JE) Medicare Administrative Contractor (MAC). In order to fulfill our contractual obligation with the Centers for Medicare & Medicaid Services (CMS), Noridian Medical Review develops a strategy using data analysis to aid in improper payment rate reduction. Noridian Medical Review performs routine data analysis to evaluate for billing utilization changes or patterns and initiates one-on-one educational letters. This letter is strictly educational in nature.

PBAL

**BRIEF OVERVIEW OF SPECIFIC CPT/HCPCS CODE COVERAGE REQUIREMENTS**

**RECOMMENDATION TO SELF-REVIEW TO DETERMINE SUFFICIENT DOCUMENTATION**

**SUMMARY OF ACTIONS TO TAKE IF DEFICIENCIES DISCOVERED**

Noridian encourages you to review the requirements for this service and evaluate for appropriateness. Please note, this letter is not a reflection of your competence as a health care professional or of the quality of care you provide to your patients. You are receiving this letter based on data analysis of billing patterns by your PTAN.

**Summary**

In summary, Noridian monitors provider billing patterns on an ongoing basis. Providers are encouraged to review Medicare Regulations to determine if documentation supports Medicare reimbursement for services which are billed in an appropriate manner. Additionally, Providers/Suppliers may consider the following actions:

- Submit voluntary refunds to Medicare for any identified overpayments.
- Provide education regarding error(s) noted to applicable staff members.
- Review and update internal controls or processes if any errors are identified.
TELEMEDICINE AND UPONCOMING CHANGES

Telemedicine – Medicare (Current)

Medicare Part B covers expenses for telehealth services on the telehealth list when those services are delivered via an interactive telecommunications system, provided certain conditions are met (42 CFR § 410.78(b)). To support rural access to care, Medicare pays for telehealth services provided through live, interactive videoconferencing between a beneficiary located at a rural originating site and a practitioner located at a distant site. An eligible originating site must be the practitioner’s office or a specified medical facility, not a beneficiary’s home or office.

https://datawarehouse.hrsa.gov/tools/analyzers/geo/Telehealth.aspx
Telemedicine – Medicare (OIG Audit)

What OIG Found:

The review found several issues associated with Medicare telehealth claims, including:

- Inconsistent documentation and lack of required documentation.
- Claims supporting the telehealth services did not always match the services provided.
- Claims for telehealth services did not always meet all required coding and documentation requirements.
- Claims were submitted for services that did not meet the field’s requirements.

How OIG Did This Review:

The OIG examined a random sample of 100 Medicare telehealth claims to determine if the claims met all of the required documentation and coding requirements. The sample was selected from a larger population of claims.

We estimated that Medicare paid for approximately $3.7 million in telehealth services that did not meet the required documentation and coding requirements.

Review of Medicare Payments for Telehealth Services

Year	Components	Report Number	Projected Error Rate (%)
2014	Office of Medicare Services	VA 03-16,076, 4-01, 4-0013	4-5%

Telemedicine – Medicare (Recent Changes)

Elimination of GT modifier for telehealth services

Effective January 1, 2018

- GT modifier no longer to be used on claims for professional services provided by telehealth (was used to signify all telehealth requirements met)
- Exception: GT modifier still required for distant site services billed under Critical Access Hospital (CAH) method II on institutional claims
- New place of service code 02 established to indicate telehealth services being billed meet all requirements
Telemedicine – Medicare (Upcoming Changes)

Bipartisan Budget Act of 2018
Effective 2019:
• Telestroke services – expanded eligible geographic and originating site
• Home dialysis patient physician visits (with in-person visits at specified intervals)
Effective 2020:
• Allowing Medicare Advantage plans to expand telehealth coverage as part of the basic benefits package
• Providers participating in certain Accountable Care Organizations (ACOs) may offer telehealth services to patients in their homes

Telemedicine – Medicare (Proposed Changes)

Medicare Physician Fee Schedule 2019 Proposed Rule
Use of “virtual technologies” – not technically telemedicine
• Virtual Check-Ins – brief non-face-to-face check-in with a patient via communication technology, to assess whether the patient’s condition necessitates an office visit
• Evaluation of Asynchronous Images and Video – review of recorded video and/or images captured by a patient in order to evaluate the patient’s condition and determine whether an office visit is necessary
• Peer-to-Peer Internet Consultations – telephone, internet or EHR consultations with treating physician without patient face-to-face contact for specific expertise

Telemedicine – Hawaii Parity
Continued Scrutiny of Device Credits

For the 114 incorrectly billed claims we identified, hospitals received $2,695,188 in Medicare overpayment. These overpayments occurred because hospitals did not have controls to identify and report re-sale replacements they received from orthotic device manufacturers.

Department of Health and Human Services
INSPECTOR GENERAL
Hospitals Did Not Always Comply With Medicare Requirements for Remitting Orthotic Device Replacements Without Cost

Hawaii Regional Conference 2018 Overview of Hot Topics in Health Care Compliance
Continued Scrutiny of Device Credits

All 296 payments reviewed for recalled cardiac medical devices did not comply with Medicare requirements for reporting manufacturer credits. Medicare contractors incorrectly paid hospitals $7.7 million for cardiac device replacement claims rather than the $3.2 million they should have been paid, resulting in potential overpayments of $4.4 million.

Overview of Hot Topics in Health Care Compliance

Regulatory citation: 42 CFR 412.89

412.89 Payment adjustment for certain replaced devices.

(a) In general. For discharges occurring on or after October 1, 2007, the amount of payment for a discharge described in paragraph (d) of this section is reduced when—

(1) A device is replaced without cost to the hospital.

(2) The provider incurs no cost for the cost of the device or

(3) The provider receives a credit equal to 50 percent or more of the cost of the device.

(b) Discharges subject to payment adjustment. (1) Payment is reduced in accordance with paragraph (a) of this section only if the explanation of the device determines that the DME has replaced.

(2) DISQ at the DMEQ is the DMEQ in the annual final rule for the hospital inpatient prospective payment system.

(c) Amount of reduction. (1) For a device provided to the hospital without cost, the cost of the device is subtracted from the DMEQ payment.
Continued Scrutiny of Device Credits

Be sure you are reporting device credits properly when submitting claims to Medicare

<table>
<thead>
<tr>
<th>Configuring Issue</th>
<th>Location</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>What Diagnosis Code do I use?</td>
<td>4B—replaced within lifecycle 60—recalled and replaced 58—replaced within lifecycle 5B—recalled and replaced 55—initially placed in clinical trial</td>
<td></td>
</tr>
<tr>
<td>What Value Code and amount do I use?</td>
<td>Fa—dollar amount of the price reduction or credit 5F—dollar amount of the price reduction or credit</td>
<td></td>
</tr>
<tr>
<td>How do I report a no-cost item?</td>
<td>If your system allows it, use $0.50 If $0.50 is not allowed, use $1.00</td>
<td></td>
</tr>
</tbody>
</table>

IMPORTANT POINT:
In OIG audits, it is important to note that they have focused not only on credits received, but also credits not pursued

PROVIDER-BASED LOCATION CHALLENGES
Provider-Based Location Challenges

Bipartisan Budget Act of 2015, Section 603
- Effective 1/1/2017, no off-campus hospital outpatient department may bill under OPPS unless:
  - Dedicated Emergency Department
  - Excepted/grandfathered

Excepted/grandfathered (must meet one of the below criteria):
- Provided and billed under OPPS for covered outpatient services prior to 11/2/2015
- On campus or within 250 yards of the main hospital or remote location of a multi-campus hospital

Provider-Based Location Challenges

Due to comments regarding billing challenges for hospitals, CMS did allow hospitals to continue to bill on the institutional claim forms (UB), allowing revenue to appear associated with the appropriate cost center
- Use modifier “PN” to designate services at non-excepted locations
- Rate paid is much lower than OPPS rate
  - 2017: 50% of OPPS rate for same services at excepted locations
  - 2018: reduction to 40% of OPPS rate
  - 2019 (proposed): remains at 40% of OPPS rate

340B PROGRAM CHANGES
The 340B Drug Pricing Program was established by Congress in 1992, with a goal of reducing the price of covered drugs for certain participating entities which, in turn, provides additional resources (by money saved) to serve underserved and indigent patients.

A recent Congressional report notes, however: "Congress did not clearly identify the intent of the program and did not clearly define parameters, leaving the statute silent on many important program requirements."

The proposed "340B Program Omnibus Guidance" ("Mega-Guidance") was issued on 8/25/2015 and included clarification on some of the areas with apparent regulatory deficiencies, including but not limited to:
- Definition of "patient"
- Registration of off-campus “child sites"
- Scope of eligible drugs
- Contract pharmacy arrangements

In part, due to the volume of comments received, the issuing agency delayed finalizing the guidance.

On 1/20/2017, the new administration withdrew the proposal as part of the overall regulatory freeze.
One thing that did change recently in the 2018 OPPS Final Rule was a downward adjustment of Medicare payment for drugs purchased through the 340B program to Average Sales Price (ASP) minus 22.5% from the prior rate of ASP plus 6%.

340B Overview of Hot Topics in Healthcare Compliance

MORE APPEARANCES OF SHARED DECISION MAKING

Shared Decision Making

Affordable Care Act, Section 3506: Program to Facilitate Shared Decision Making

January 5, 2010

CMS Beneficiary Engagement and Incentives (BEE) Models

Shared Decision Making (SDM) Model

December 8, 2016

• Applies to Accountable Care Organizations (ACO)

• Hospitals engaged through requirements of NCDs
### NCD 210.14 Lung Cancer Screening with Low Dose Computed Tomography

**B. Nationally Covered Indications**

Counseling and Shared Decision Making Visit

Before the beneficiary’s first lung cancer LDCT screening, the beneficiary must receive a counseling and shared decision making visit that meets all of the following criteria, and is appropriately documented in the beneficiary’s medical records:

- Must include all of the following elements:
  - **Shared decision making**, including the use of one or more decision aids, to include benefits and harms of screening, follow-up diagnostic testing, over-diagnosis, false positive rate, and total radiation exposure.

### More Shared Decision Making in NCDs

- **NCD 20.34 Percutaneous Left Atrial Appendage Closure (LAAC)**
  
  Effective 2/8/2016

- **Decision Memo for Implantable Cardioverter Defibrillators CAG-00157R4**
  
  Dated 2/15/2018

### NCD 20.34 Percutaneous Left Atrial Appendage Closure (LAAC)

The Centers for Medicare & Medicaid Services (CMS) covers percutaneous LAAC for non-valvular atrial fibrillation (NVAF) through Coverage with Evidence Development (CED) with the following conditions:

- A formal shared decision making interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation in patients with NVAF prior to LAAC. Additionally, the shared decision making interaction must be documented in the medical record.
Decision Memo for Implantable Automatic Defibrillators (CAG-00157R4)  
CMS is finalizing relatively minimal changes to the ICD-NCD 20.4 from the 2005 reconsideration. The Decision Memo issued on February 15, 2018 includes the following changes to the NCD:

- Patient Criteria
  - <...>
  - Require a patient shared decision making (SDM) interaction prior to ICD implantation for certain patients.

AND OTHERS!

NO INPATIENT ADMISSION ORDER NEEDED???


"...it has come to our attention that some otherwise medically necessary inpatient admissions are being denied payment due to technical discrepancies with the documentation of inpatient admission orders. Common technical discrepancies consist of missing practitioner admission signatures, missing co-signatures or authentication signatures, and signatures occurring after discharge."  

"...we have concluded that if the hospital is operating in accordance with the hospital CoPs, medical reviews should primarily focus on whether the inpatient was medically reasonable and necessary rather than occasional inadvertent signature documentation issues unrelated to the medical necessity of the inpatient stay."
NO INPATIENT ADMISSION ORDER NEEDED???

2019 IPPS Final Rule published in the Federal Register August 17, 2018
- Removing requirement that written inpatient admission orders are a specific requirement for Part A payment
- Other available documentation, i.e. physician certification statement when required, progress notes, or the medical record as a whole can support that all coverage criteria (including medical necessity) are met if the hospital is operating in accordance with CoPs
- No change in the requirement that the patient must be formally admitted as an inpatient under an order for inpatient admission, just no denial of payment for technical discrepancies for signature and/or signature timing issues if supported by physician admission and progress notes and other documentation
- CMS believes that technically defective orders are rare
- This does NOT change the "two-midnight" payment policy

E&Ms FOR OFFICE/OUTPATIENT SETTINGS

2019 MPFS Proposed Rule
- Single payment rate for E&M visit levels 2-5
  - Add on payments for inherent complexity for primary care services, inherent complexity associated with certain non-procedural services, prolonged visit
  - Multiple procedure payment adjustment when furnished with procedure on same day

IMAGING – Appropriate Use Criteria (AUC)

Protecting Access to Medicare Act of 2014 (PAMA) - established a program requiring adherence to AUC using clinical decision support (CDS) for advanced imaging services

Components (as originally established):
- Establishment of AUC by 11/15/2015 COMPLETE
- Specification of CDS mechanisms for consultation with AUC by 4/1/2016 COMPLETE
- AUC consultation by ordering professionals and reporting on AUC consultation by furnishing professionals by 1/1/2017 DELAYED
- Annually identify outlier ordering professionals for services after 1/1/2017 DELAYED
Current status (MPFS 2018 Final Rule):

- AUC consultation and reporting requirements effective for services provided on or after 1/1/2020, and reflected on claim using ordering practitioner NPI and designated modifier
- Voluntary reporting period for “early adopters” 7/1/2018 – 12/31/2019
- Educational and operations testing 1/1/2020 – 12/31/2020 where claim will be paid regardless of whether AUC consultation is correctly included on claim
  - “We hope practitioners will use this time to make good faith efforts to accurately report information on the claim”

More details are in this document.