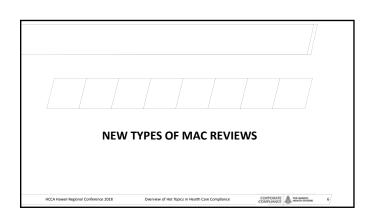


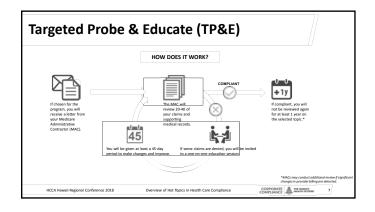
Th	e Queen's Health Sy	stems	
M	The Queen's Medical Center Level 1 Trauma Center located in downtow 575 acute beds Admissions 24.996 Et visits 55.854 OP visits 314,351	_	Molokai 15 bed rural health care facility Admissions 95 ER visits 5,278
M	The Queen's Medical Center - West O'ahu - Community hospital located in 'Ewa - Admissions 4,597 - Revists 52,850 - OP visits 44,019	69	North Hawa'l Community Hospital • Rural acute care in Wainnea on Hawa'l • Admissions 1,707 • ER 14,20 wisits • OP 55,431 • Home Health affiliate
	HCCA Regional Conference, Oct 2018	Overview of Hot Topics in Health Care Complia	DICE CORPORATE

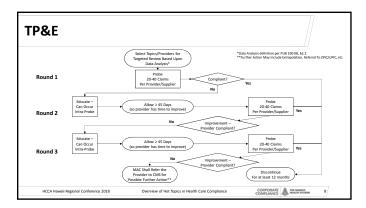
The	e Queen's Health	Systems	
	Diagnostic Laboratory Services, Inc. Locally owned and operated commercial laboratory Over 40 locations statewide	Queen's Insurance Exchange, Inc. • Provides liability insurance coverage for QHS and affiliates	Queen's Clinically Integrated Physician Network • Physician-led network transforming health care by developing and adopting clinical best practices
d	Queen Emma Land Company • Manages and enhances the income- generating potential of lands left to The Queen's Hospital by Queen Emma, and additional properties owned by OHS	CareResource Hawai'i Delivers home based and community health care, serving Oahu, Molokai, Maui and Hawaii Island.	Queen's 'Akoakoa, LLC • Accountable Care Organization • Quality improvement, knowledge and support, and successful payment models
	Queen's Development Corporation • Manages Queen's Health Care Centers with 7 locations on Oahu, Big Island and Kauai; POBs; OP pharmacles & parking garages	Hamamatsu/Queen's PET Imaging Center, LLC • Maintains and operates a positron emission tomography (PET) research and diagnostic imaging center (the PET Center)	Queen's MSSP ACO, LLC • Accountable Care Organization: Medicare program created to encourage health care providers and entitles to work together to improve patient health and reduce unnecessary costs of care
	HCCA Regional Conference, Oct 2018	Overview of Hot Topics in Health Care Compliance	CORPORATE THE OURDING 3

Objectives		
	not topics that keep showing up wi n the enforcement community	th regulators
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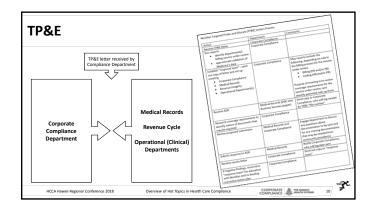
Agenda	
New Types of MAC Reviews Telemedicine and upcoming changes Continued scrutiny of device credits Provider-Based location challenges 340B program changes More appearances of Shared Decision Making And Others!	
HCCA Hawaii Regional Conference 2018 Overview of Hot Topics in Health Care Compliance	CORPORATE THE GUESTS 5

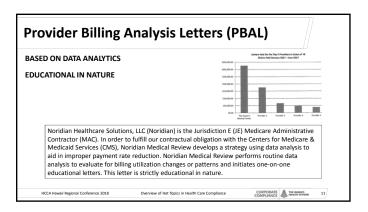






TP&E WHAT ARE SOME COMMON CLAIM ERRORS? • Missing or incomplete orders or certifications/recertification • Expired orders or certifications/recertification, encounter note • Signature missing on order, certification/recertification, encounter note • Documentation does not meet medical necessity (NCD, 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.





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 deducation regarding error(s) noted to applicable staff members. Review and update internal controls or processes if any errors are identified.

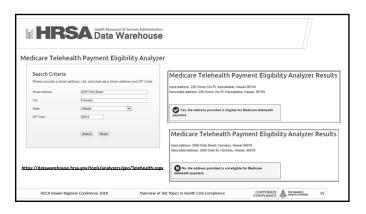
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Telemedicine – Medicare (Current)

Medicare Part B covers expenses for telehealth services on the <u>telehealth list</u> when those services are delivered via an <u>interactive telecommunications system</u>, 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 <u>beneficiary located at a rural originating site</u> and a <u>practitioner located at a distant site</u>. An <u>eligible originating site</u> must be the practitioner's office or a specified medical facility, not a beneficiary's home or office.

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lemedicine –	Medicare (OIG Audit)
Department of Health and Human Services OFFICE OF INSPECTOR GENERAL	What OIG Found CMs paid practitioners for some telehealth claims associated with services that do not meet Medicaire requirements. For 60 of the 100 claims in our sample, telehealth services met requirements. However, for the remaining 3 claim, serviced did not meet requirements. Services for the remaining 3 claim.
CMS PAID PRACTITIONERS FOR TREEBEALTH SERVICES PHAT DID NOT MEET MEDICARE REQUIREMENTS	How OIG Did This Review We reviewed 191.118 Medicare paid distant-site televisht claims, totaling \$1.88 million, that did not have corresponding originating site claims. We reviewed provider supporting arounds supplied 100 claims to determine whether services were allowable in accordance with Medicare requirements. **I claim was for a noncovered service, and **1 claim was for services provided by an unallowable means of communication. **I claim was for a noncovered service, and **1 claim was for services provided by a physician located outside the United States. We estimated that Medicare could have seved approximately \$1.7 million during our wasting period in practitioners had provided teithealths services in accordance with Medicare requirements.
HCCA Hawaii Regional Conference 2018	Overview of Hot Topics in Health Care Compliance COMPLIANCE IN HOLDINGS 16

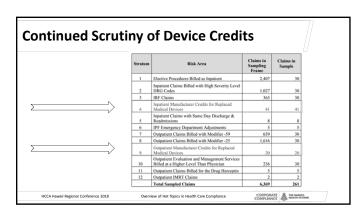
Review of	Medicare Payments	for Telehealth Service	es .				
	certain conditions are med (ECLTR § 410 780)). To support rural access to care, Moderare pays for telehealth services provided through live, interactive videoconferencing between a beneficiary pointed at an autil anging						
office or a specifie have corresponding	d medical facility, not a beneficiary's l ig claims from originating sites to deb	home or office. We will review Medicare ermine whether those services met Med	claims paid for telehe dicare requirements.	aith services provided at dis	stant sites that do not		
office or a specifie have correspondir Announced or	d medical facility, not a beneficiary's i g claims from originating sites to det Agency	home or office. We will review Medicare ermine whether those services met Med	claims paid for telehe dicare requirements.	aith services provided at dis	tant sites that do not		

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 MCCA Howald Regional Conference 2018 Overview of Hot Topics in Health Care Compliance

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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 	
HCCA Hawaii Regional Conference 2018 Overview of Hot Topics in Health Care Compilance CONFIGURACE AND INCOMPLY AND INCOMPL	
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	
HCCA Hawaii Regional Conference 2018 Overview of Hot Topics in Health Care Compliance COMPLIANCE And Associations COMPLIANCE And Associations	
Telemedicine – Hawaii Parity	
\$431:10A:116.3 Coverage for telehealth. (a) It is the intent of the legislature to recognize the application of telehealth as a reimbursable service by which as individual shall receive medical services from a health care provider (b). (b) and a conclosurate of the provider telephone the conclosurate plant by a state of the conclosurate plant by a state is assess, sendend, or removed shall require face-to-	
b) No localisms and health or minimum plan that is issued, amended, or removed thall require fasework face contact between a health care provider and a patient as a precequist of represent for sorrives appropriately provided through teshebalth in accordance with penerally accepted health care practices and standards provided in the provided through teshebalth care provided through teshebalth care provided through teshebalth care provided them and conditions of the plan agreed upon mong the entroller or subscriber, the insurer, and the health care provided the provided through teshebalth shall be equivalent to estabutement for the same services provided vizi face-to-face contact between a health care provided vizi face-to-face contact between a health care provider and a patient. Nothing in this section shall	
require a health care provider to be physically present with the patient at an originating site unless a health care provider at the distant site deems it necessary.	
\$132:1-601.5 Cowrange for telebealth. (a) It is the intent of the legislature to recognize the application of telebealth as a reimbursable service by which an individual half receive medical services from a health care provider without face-to-face contact with the health care provider. (b) No jurnal headth careliety plain that is issued, amended, or renewed shall require face-to-face contact between a beath care provider and a pation; as a precequiate for payment for services appropriately provided through provided through the provided community at the time the services were provided. The coverage required in this servicion may be subject to subject to	
professional community at the time the services were provided. The coverage required in this section may be subject to	I

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Telemedicine – Hawaii Parity		
\$4120-23.5 Coverage for telehealth. (a) It is the intent of the legislature to recognize the application of telehealth as a reimbursable service by which an individual shall receive medical services from a health care provider without face-to-face-contact with the health care provider.		
without face-to-face contact with the health care provider. (b) No health maintenance organization plan that is issued, amended, or renewed shall require face-to-face contact between a health care provider and a parient as a negranulate for payment for earliers appropriately provided through		
various tase-contact contact thin the heading provider. (b) No bealth minimannow organization plant that is issued, amended, or renewed shall require face-to-face contact between a health care provider and a patient as a precequisite for payment for services appropriately provided through teshealth in a coordance with generally accepted health care practices and standards prevailing in the applicable professional community at the time the services were provided. The coverage required in this section may be subject to all terms and conditions of the plan agreed upon among the enrolled or subscribes, the health antennance organization,		
all terms and conditions of the plan agreed upon among the enrollee or subscriber, the health maintenance organization, and the health care provider.		
in the provided in the services provided through telebalth shall be provided in Services provided through telebalth shall be provided on Services provided on Services provided on Services, provided on Services, the services provided on Services, the services shall require a health care provider and a Services, the services shall require a health care provider at the distant wind deems in necessary.		
(5346-9-1) Coverage for telehealth. (a) The State's medicals managed care and fear-for-earlier propound shall of deep coverage for any service provided through telepacity through the constitution between a patient and a health care provider. (b) [Rindbursement] for services provided through telehealth that hall be equivalent to reindursement for the same		
n-person consultation between a patient and a health care provider. (b) Reimbursement for services provided through telehealth shall be equivalent to reimbursement for the same		
in industriement for services provided through saleshealth status servering that to estimate the test seal to the services provided through saleshealth status servering the services of the s		•
(d) There shall be no restrictions on originating site requirements for telehealth coverage or reimbursement under this section.	·	
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INSPECTOR GENERAL	1	
HOSPITALS DID NOT ALWAYS COMPLY	l	
WITH MEDICARE REQUIREMENTS FOR		
REPORTING COCHLEAR DEVICES REPLACED WITHOUT COST	1	
For the 116 incorrectly billed claims we identified, hospitals received \$2,685,588 in Medicare	l 	
overpayments. These overpayments occurred because hospitals did not have controls to identify and report no-cost replacements they received from cochlear device manufacturers.	1	
Impares abor dis apper me in existence of set (file	1	
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Continued Scrutiny of Device	Credits
	Department of Health and Human Services of prince of INSPECTION CENTRAL HOSPITALS DID NOT COMPLE WITH MEDICARE REQUIREMENTS FOR
All 296 payments reviewed for recalled cardiac medical devices did not comy with Medicare requirements for reporting manufacturer credits. Medicare contractors incorrectly paid hospitals \$7.7 million for cardiac device replacer claims rather than the \$3.3 million they should have been paid, resulting in potential overpayments of \$4.4 million.	
HCCA Hawaii Regional Conference 2018 Overview of Hot Topics in Health Care Con	mpliance CORPORATE & PHI OURSIN'S COMPLIANCE HALIN SYSTEMS



Continued Scruti	ny of Device Credi	ts
Regulatory citation: 42 CFR 412	2.89	
§412.89 Payment adjustment for cer	tain replaced devices.	
(a) General rule. For discharges occidescribed in paragraph (b) of this section	urring on or after October 1, 2007, the amount of payn n is reduced when—	nent for a discharge
(1) A device is replaced without cost	to the hospital;	
(2) The provider received full credit		
(3) The provider receives a credit eq	ual to 50 percent or more of the cost of the device.	
(b) Discharges subject to payment a section only if the implantation of the de	paragraph (a) of this	
(2) CMS lists the DRGs that qualify u inpatient prospective payment system.	rule for the hospital	
(c) Amount of reduction. (1) For a defrom the DRG payment.	evice provided to the hospital without cost, the cost of	the device is subtracted
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Continued Scrutiny of Device Credits	
Be sure you are reporting device credits properly when submitting claims to Medicare	
Coding/Billing Issue Inpatient Outpatient What Condition Code do I use? 49—replaced within lifecycle 50—recalled and replaced 50—recalled and repl	
50—recalled and replaced 50—recalled and replaced 50—recalled and replaced 53—initially placed in clinical trial FD—dollar amount of the price reduction or credit FD—dollar amount or credit	
How do I report a no-cost item charge? If your system allows it, use \$0.00 If \$0.00 is not allowed, If \$0.00 is not allowed,	
use \$1.00 use \$1.00	
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	-
Continued Scrutiny of Device Credits	
IMPORTANT POINT:	
In OIG audits, it is important to note that they have focused not only on credits received, but also credits <u>not pursued</u>	
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PROVIDED DASED LOCATION GUALLENGES	
PROVIDER-BASED LOCATION CHALLENGES	
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## 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 multicampus hospital

Overview of Hot Topics in Health Care Compliance

### 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

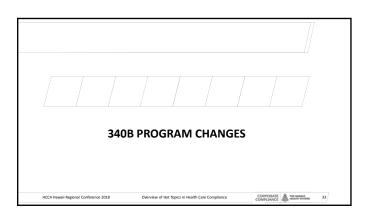
- Use modifier "PN" to designate services at non-excepted locations
- Rate paid is much lower than OPPS rate
  - 2017: 50% of OPPS rate for same services at excepted locations
  - 2018: reduction to 40% of OPPS rate
  - 2019 (proposed): remains at 40% of OPPS rate

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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 reports notes, however:

"Congress did not clearly identify the intent of the program and did not identify clear parameters, leaving the statute silent on many important program requirements."



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### 340B

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

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### 340B

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.



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340B	
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%.	
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MORE APPEARANCES OF SHARED DECISION MAKING	
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Shared Desision Making	
Shared Decision Making	
Affordable Care Act, Section 3506:	
Program to Facilitate Shared Decision Making	
January 5, 2010	
CMS Beneficiary Engagement and Incentives (BEI) Models	
Shared Decision Making (SDM) Model	
December 8, 2016	
Applies to Accountable Care Organizations (ACO)	
<ul> <li>Hospitals engaged through requirements of NCDs</li> </ul>	
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NCD 210.14 Lung Cancer Screening with Low	
Dose Computed Tomography  NCD Updated January 24, 2017 Effective February 5, 2015	
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 <b>shared decision making visit</b> 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	-
HCCA Hawaii Regional Conference 2018 Overview of Hot Topics in Health Care Compliance COMPLIANCE & the Outlook Hot Topics in Health Care Compliance 40	
	1
More Shared Decision Making in NCDs	
NCD 20.34 Percutaneous Left Atrial Appendage Closure (LAAC)	
Effective 2/8/2016	
Effective 2/6/2010	
Decicion Mama for Implantable Cardioverter Defibrillators CAC 0015784	-
Decision Memo for Implantable Cardioverter Defibrillators CAG-00157R4	
Dated 2/15/2018	
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HCCA Hawaii Regional Conference 2018 Overview of Hot Topics in Health Care Compliance COMPUNICE AND THREE MACRITICITIES 41	
	•
NCD 20.34 Percutaneous Left Atrial Appendage	
CIOSUIE (LAAC) Effective February 8, 2016	
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:	
<>	
The patient must have:	
The patient must have:	
The patient must have: <>	
·	
A formal shared decision making interaction with an independent non-interventional physician <u>using an evidence-based decision tool</u> on oral anticoagulation in patients with	
A formal shared decision making interaction with an independent non-interventional physician <u>using an evidence-based decision tool</u> on oral anticoagulation in patients with NVAF prior to LAAC. Additionally, the shared decision making interaction must be	
A formal shared decision making interaction with an independent non-interventional physician <u>using an evidence-based decision tool</u> on oral anticoagulation in patients with	
A formal shared decision making interaction with an independent non-interventional physician <u>using an evidence-based decision tool</u> on oral anticoagulation in patients with NVAF prior to LAAC. Additionally, the shared decision making interaction must be	
A formal shared decision making interaction with an independent non-interventional physician <u>using an evidence-based decision tool</u> on oral anticoagulation in patients with NVAF prior to LAAC. Additionally, the shared decision making interaction must be <u>documented in the medical record.</u>	
<u>  • A formal shared decision making interaction with an independent non-interventional physician <u>using an evidence-based decision tool</u> on oral anticoagulation in patients with NVAF prior to LAAC. Additionally, the shared decision making interaction must be <u>documented in the medical record</u>.</u>	

Decision Memo for Implantable Automatic	
Defibrillators (CAG-00157R4)  Daled February 15, 2018	
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.	
HCCA Hawaii Regional Conference 2018 Overview of Hot Topics in Health Care Compliance COMPLIANCE AND MAINTENNESS 43	
AND OTHERS!	
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COMPLIANCE The administration of the control of the	
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NO INPATIENT ADMISSION ORDER NEEDED???	
2010 IDDS Drongered Dule mublished in the Federal Desister May 7 2010 (masses 11)	
2019 IPPS Proposed Rule published in the Federal Register May 7, 2018 (preamble):	
" 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."	
5 ,	
"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."	
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### 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



Reduced documentation requirements – focus on Medical Decision Making and/or time
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### **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
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   Overview of Het Regics in Health Care Compliance
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### **IMAGING – Appropriate Use Criteria (AUC)**

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"

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