

Organizational PA and NP Policy Considerations



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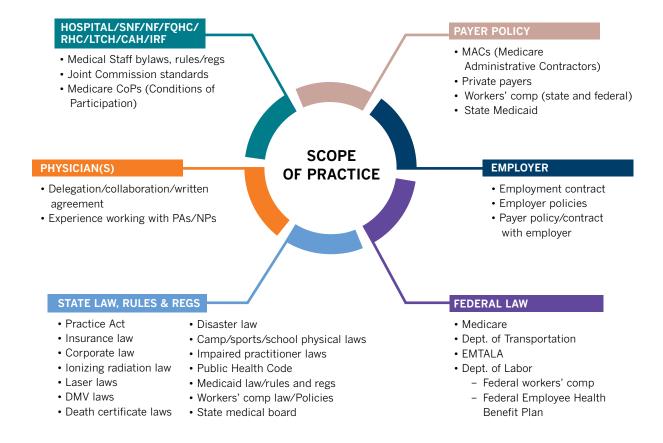
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All practitioners must determine what rules apply to the services they provide, in each setting they provide them, the impact the rules have on their ability to practice, and what they can do to ensure compliance. The list of policies and regulations seems endless. Federal and state law, accrediting and certifying bodies, payer policies, facility and employer policies, and medical staff bylaws or rules and regulations are just the beginning. The rules vary by practice setting, such as an inpatient or outpatient hospital, ambulatory surgical center, critical access hospital, federally qualified health center, rural health facility, skilled nursing facility, nursing facility, inpatient rehabilitation facility, or in the patient's home. Practitioners who are federally employed are required to follow another set of rules entirely.



Many regulations or laws were written long before the PA and NP professions were established. As a result, some policies do not include them in the language. By virtue of not mentioning PAs, for example, some policies serve to exclude them, despite the belief that the physician's delegatory authority – as conferred by state law – should override any omissions in regulations and authorize a PA to perform any delegated tasks.

In this era of healthcare workforce shortages and limited patient access to care, it is important to break down unnecessary barriers and allow PAs and NPs to practice to their maximum potential, within the confines of the rules. This means that the myths and urban legends surrounding PA and NP regulations must be eradicated. Of course, PAs and NPs can perform

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new patient visits in most situations; apply the proper billing rules to the setting and the payer. Yes, there are situations where chart entries may require cosignature. The key is finding the relevant regulations and knowing when and in what setting they apply.

It all starts at the practice level, when a PA or NP is prohibited from signing a form, providing a certain service or seeing a certain type of patient. Well, who says? Upon which regulation or law or policy is that based? Dispelling the myths and misinformation is an important step in eradicating the barriers to providing care.

- First and foremost, patient care should be provided by the right person(s) at the right time in the right setting. After providing the absolute best possible care, determine how the claim should be submitted for payment. The delivery of patient care should not solely be driven by billing rules.
- Do not accept any assertion as fact. Ask for the regulatory reference, or at the very least, find out if it comes from state law or payer policy, the Joint Commission, or facility policy.
- Do not pass up an opportunity to educate someone about PA or NP practice. Good information is a powerful tool and a good way to foster a dialogue. Know your resources to become the subject matter expert in your organization.
- Consultants or mock surveyors can sometimes provide incomplete or inaccurate information. Insist on seeing the regulation to support any claim that a PA or NP cannot do something.
- Review hospital bylaws, rules, regulations and clinical policies for unnecessary restrictions or barriers to practice. There may be an opportunity to improve utilization of PAs and NPs simply by updating some antiquated policies.
- The experts at CHLM can help you navigate these regulations and provide direction to your organization.

All the best,

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The content presented is for informational purposes only, and nothing herein is intended to be, or shall be construed as, legal or medical advice, or as a substitute for legal or medical advice. All information is being provided AS IS, and any reliance on such information is expressly at your own risk.

The information was current at the time it was submitted.

Although every reasonable effort has been made to assure the accuracy of the information herein, the ultimate responsibility for compliance with accreditation and facility standards, the correct submission of claims and response to any remittance advice lies with the provider of services.



Compliance Considerations

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Hospital-Employed PAs and NPs: Medicare Part A Cost Reporting and Part B Enrollment

Introduction

PAs and NPs Recognized by Medicare - The Balanced Budget Act of 1997

Prior to the implementation of the Balanced Budget Act of 1997 (BBA), payment for services provided by PAs and NPs were considered bundled in hospital inpatient and outpatient Part A services; PAs and NPs were considered facility support staff.¹ Effective January 1, 1998, sections 4511 and 4512 of the BBA amended section 1861(b)(4) of the Social Security Act expanding the recognition of services provided by PAs and NPs under the Medicare program as Part B (physician) professional services, specifically excluding their services as Part A services (hospital services) in the hospital inpatient settings.²,³,4,5 The resultant Medicare program coverage and payment regulations and policies promulgated by The Centers for Medicare and Medicaid Services (CMS) of the United States (U.S.) Department of Health and

¹ Medicare Payment Advisory Commission, A Data Book: Healthcare Spending and the Medicare Program (June 2015) at 7;

[&]quot;Also, no separate payment was made for the professional services of NPs, CNSs, and PAs furnished to hospital inpatients because these services to hospital inpatients were bundled into the payment that hospitals received for "hospital services" and billed under the hospital's cost report."

² See Balanced Budget Act Of 1997, § 4511 Increased Medicare Reimbursement For Nurse Practitioners And Clinical Nurse Specialists And § 4512 Increased Medicare Reimbursement For Physician Assistants, available at http://www.gpo.gov/fdsys/pkg/PLAW-105publ33/pdf/PLAW-105publ33.pdf at 192-194.

³ 42 U.S.C 1861(b)(4).

⁴ 42 C.F.R. §409.10: "(b) *Inpatient hospital services* does not include the following types of services: (4) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.*

⁽⁵⁾ Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act."

⁵ Dep't of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS), CMS Manual System, Pub.100-04 Medicare Claims Processing, TRANSMITTAL 1168 Change Request 5221: Direct Billing and Payment for Nonphysician Practitioner Services Furnished to Hospital Inpatients and Outpatients (January 26, 2007), [hereinafter transmittal 1168] at 2, available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1168CP.pdf

[&]quot;Section 4511(a)(2)(B) of the Balanced Budget Act of 1997 amended §1861(b)(4) of the Social Security Act to exclude the professional services of nurse practitioners (NPs), clinical nurse specialists (CNSs) and physician assistants (PAs) from hospital services."

Human Services (HHS) define professional services provided by PAs ^{6,7} and NPs ^{8,9} as those typically provided by physicians.

With the implementation of the BBA, PAs and NPs became enrolled providers in the Medicare program with unique provider identification numbers, eligible to provide professional Part B services in all settings. Effective January 6, 2014, as a provision of the PPACA, all providers, including PAs and NPs, are required to enroll in the Medicare program with their National Provider Identifier (NPI) for the purposes of ordering, referring and/or providing professional medical services for Medicare beneficiaries.¹⁰

BBA Regulatory Considerations

Medicare Part A Hospital Cost Report

Hospitals participating in the Medicare program must file annual cost reports via CMS Form 2552, providing information on facility characteristics, services and utilization data, financial statements, and costs, charges, and revenue by cost center. A consequence of the BBA for hospitals and health systems directly employing PAs and NPs is that, since 1998, the wages employment costs of the PAs and NPs who are providing professional medical services should not be factored into the hospital's Medicare Part A cost report, as those services must be billed to the Medicare program under Part B. 12, 13 Failure to remove the clinical PA and NP salaries



⁶ Centers for Medicare and Medicaid Services, *Medicare Benefit Policy Manual, Chapter 15: Covered Medical and Other Health Services, §190 Physician Assistant (PA) Services,* B. (1): "The services of a PA may be covered under Part B, if all of the following requirements are met: They are the types that are considered physician's services if furnished by a doctor of medicine or osteopathy (MD/DO)." *Available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf*

"Unsupported Costs for Part B Services

The Social Security Act and Medicare regulations provide that, as a general matter, the costs of services provided by nurse practitioners and clinical social workers are covered by Part B, not Part A. The Manual, part II, section 3605, requires hospitals to exclude from their reported wage index information those nurse practitioner and other services that hospitals claim for Part B reimbursement as patient services. Under Medicare, these services are related to patient care and are billed separately under Part B."

⁷ 42 C.F.R §410.74.

⁸ Centers For Medicare And Medicaid Services, *Medicare Benefit Policy Manual, Chapter 15: Covered Medical and Other Health Services, §200 Nurse Practitioner (NP) Services,* B. (1): "The services of an NP may be covered under Part B if all of the following conditions are met: They are the types that are considered physician's services if furnished by a doctor of medicine or osteopathy (MD/DO)." *Available at* http://www.cms.gov/Regulations-and-Guidance/Manuals/downloads/bp102c15.pdf

⁹ 42 C.F.R. §410.75.

See generally, Centers for Medicare and Medicaid Services, Full Implementation of Edits on the Ordering/Referring Providers in Medicare Part B, DME, and Part A Home Health Agency (HHA) Claims (January 2015) MLN Matters SE 1305 Revised, Available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1305.pdf

¹¹ 42 U.S.C §1395g and 42 C.F.R. §413.20(b).

¹² See 42 C.F.R. § 409.10 (b), "Inpatient hospital services does not include...: (4) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act. (5) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act."

¹³ See also U.S. Dep't of Health and Human Services, Office of Audit Services, OIG Report: Review of Duke University Medical Center's Reported Fiscal Year 2006 Wage Data (A-OI-07-00511)April 2008, available at https://oig.hhs.gov/oas/reports/region1/10700511.pdf at 4:

from the Part A cost report calculation, (thereby filing a what might be considered a false report to the Medicare program), can result in significant liability, including "criminal, civil and administrative action" for the organization, as indicated by the warning advisory found in the preface of the form. ¹⁴ The filing organization's representative also must certify that the expenses identified in the report are allowable, attest to the accuracy of the information in the report, and that the data provided is in compliance with all applicable laws. ¹⁵

Medicare Part B Enrollment and Payment Policy

A claim for Part B services provided by the PA or NP must be submitted to the Medicare program via CMS Form-1500-Health Insurance Claim Form. 16 The PA/NP (and physicians) must be currently enrolled in the Medicare program in order to submit those claims. 17

For PAs, the claim is submitted identifying the PA as the provider of services; however, the payment cannot be paid directly to the PA.¹⁸ Payment for professional medical services provided to Medicare beneficiaries by PAs must be paid directly to the employer of the PA.^{19, 20} Payment for professional services provided to Medicare beneficiaries by NPs can be paid

¹⁴ See Form CMS-2552-10, Hospital and Healthcare Complex Cost Report Certification and Settlement Summary, available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3P240f.pdf

[&]quot;Misrepresentation Or Falsification Of Any Information Contained In This Cost Report May Be Punishable By Criminal, Civil And Administrative Action, Fine And/Or Imprisonment Under Federal Law. Furthermore, If Services Identified In This Report Were Provided Or Procured Through The Payment Directly Or Indirectly Of A Kickback Or Were Otherwise Illegal, Criminal, Civil And Administrative Action, Fines And/Or Imprisonment May Result."

¹⁵ *Id.*, "I HEREBY CERTIFY that I have read the above certification statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by ______{Provider Name(s)} and Number(s)} for the cost reporting period beginning ____and ending ____ and to the best of my knowledge and belief, this report and statement are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations."

^{16 42} C.F.R. § 424.32.

¹⁷ Supra note 10.

¹⁸ Centers for Medicare and Medicaid Services, Medicare Claims Processing Manual, Pub. 100-04, Chapter 12 §110.4 (A.), available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf

[&]quot;PA Identification: PAs must have their own "nonphysician practitioner" national provider identification number (NPI) number. This NPI is used for identification purposes only when billing for PA services, because only an appropriate PA employer or, a provider/supplier for whom the PA furnishes services as an independent contractor can bill for PA services."

¹⁹ Centers for Medicare and Medicaid Services, *Medicare Program Integrity Manual*, Chapter 15, §15.4.4.12, *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c15.pdf

[&]quot;Payment for the PA's services may only be made to the PA's employer, not to the PA himself/herself... This also means that the PA does not reassign his or her benefits to the employer, since the employer must receive direct payment anyway.

²⁰ Centers for Medicare and Medicaid Services, *Medicare Benefit Policy Manual*, Pub. 100-02, Chapter 15, §190(D), available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf

[&]quot;Employment Relationship: Payment for the services of a PA may be made only to the actual qualified employer of the PA that is eligible to enroll in the Medicare program under existing Medicare provider/supplier categories."

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payment for services provided by PAs and NPs, allowing for NPs to reassign payment to their employer. This same guidance also describes the hospital's obligation to bill for the services provided by PAs they employ. Further clarification was subsequently published by CMS: Section 4511(a)(2)(B) of the Balanced Budget Act of 1997 amended section 1861(b)(4)

directly to the NP.21 CMS issued additional guidance for hospitals regarding billing and

Section 4511(a)(2)(B) of the Balanced Budget Act of 1997 amended section 1861(b)(4) of the Social Security Act to exclude the professional services of NPs, CNSs and PAs from hospital inpatient services. Accordingly, upon the effective date of Change Request (CR) 5221, NPs and CNSs are authorized to bill Medicare carriers directly for their professional services when furnished to hospital patients, both inpatients and outpatients. The employer of a PA, rather than the hospital, must bill the carrier for their professional services when furnished to hospital patients. Hospitals should not bill for the professional services of a PA, unless the PA is employed by the hospital... Hospitals may bill the carrier for the professional services of an NP or a CNS furnished to hospital inpatients and outpatients when payment for the NP and CNS services has been reassigned to the hospital... ²⁴

- ²¹ Centers for Medicare and Medicaid Services, *Medicare Claims Processing Manual*, Pub. 100-04, Chapter 12 § 120.3 (B), available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf
 - "... Payment may be made directly to a NP or CNS for their professional services when furnished in collaboration with a physician." $\frac{1}{2}$
- ²² Dep't of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS), CMS Manual System, Pub.100-04 Medicare Claims Processing, TRANSMITTAL 1168 Change Request 5221: Direct Billing and Payment for Nonphysician Practitioner Services Furnished to Hospital Inpatients and Outpatients (January 26, 2007), available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1168CP.pdf
 - "Accordingly, direct billing and payment for the professional services of NPs and CNSs furnished to hospital patients (inpatients and outpatients) must be made to the NP or the CNS. However, if NPs or CNSs reassign payment to the hospital for their professional services to hospital patients, payment must be made to the hospital for these services at 85% of the physician fee schedule. Payment for NP and CNS services is made only on an assignment-related basis."

²³ Id.:

- "The employer or contractor of a PA must bill the Part B carrier for the professional services of PA's furnished to hospital patients and payment is always made to the PA's employer or contractor at 85% of the physician fee schedule. Since PAs cannot bill the program directly for their professional services, they do not have the option to reassign payment for their professional services to their employer or contractor. However, in the case where a hospital is the PA's employer or contractor, the hospital must bill the program for the PA's professional services furnished to its patient."
- ²⁴ Centers for Medicare and Medicaid Services, Direct Billing and Payment for Non-Physician Practitioner (NPP) Services Furnished to Hospital Inpatients and Outpatients MLN Matters Number MM522, 1-2, available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM5221.pdf

Enforcement Activity

In 2008, the Office of Audit Services of the Office of the Inspector General at the Department of Health and Human Services issued a report entitled *Review of Duke University Medical Center's Reported Fiscal Year 2006 Wage Data*²⁵ that provides further guidance with regards to PAs and NPs and the Medicare Part A cost report:

The Social Security Act and Medicare regulations provide that, as a general matter, the costs of services provided by nurse practitioners and clinical social workers are covered by Part B, not Part A.²⁶ The Manual, part II, section 3605, requires hospitals to exclude from their reported wage index information those nurse practitioner and other services that hospitals claim for Part B reimbursement as patient services. Under Medicare, these services are related to patient care and are billed separately under Part B.

Why is This Report Important?

OIG actions provide insight into how regulations are interpreted by the agency. This report would likely elevate perception of the risk to the organization and suggest review of their cost reporting calculations. The more recent Department of Justice settlement in the University of Louisville 2013 case²⁷ further suggests that the salaries of PAs and NPs performing Part B services should not be included in the wage calculations for the Part A cost report.

²⁵ Dep't of Health and Human Services (HHS), Office of the Inspector General, Review of Duke University Medical Center's Reported Fiscal Year 2006 Wage Data (A-OI-07-00511), https://oig.hhs.gov/oas/reports/region1/10700511.pdf

²⁶ Section 1861(s)(2)(K)(ii) of the Act and 42 CFR § 410.75 include care by nurse practitioners as covered Part B services; section 1861(b)(4) of the Act and 42 CFR § 409.10(b)(5) exclude nurse practitioners from Part A inpatient hospital services.

²⁷ U.S. Department of Justice, Western District of Kentucky, USAO Press Release, *Operators Of University Of Louisville Hospital To Pay* \$2,833,408.60 To Settle False Medicare Billings, July 1, 2013. Available at: https://www.justice.gov/usao-wdky/pr/operators-university-louisville-hospital-pay-283340860-settle-false-medicare-billings

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Hospital-Employed PAs and NPs: Employment Relationship, Physician Self-Referral/Stark Law and Anti-Kickback Statute Liability

Employment Relationships and Utilization of PAs/NPs:

Under the Medicare program, services provided by PAs and APRNs are defined as those typically provided by physicians^{1,2,3,4} and therefore are covered under Medicare Part B. Since the implementation of the Balanced Budget Act of 1997, PAs and APRNs are no longer considered inpatient facility clinical "support staff" and their salaries may no longer be factored into the Medicare A facility cost report.⁵

For PAs, the claim is submitted identifying the PA as the provider of services; however, the payment cannot be paid directly to the PA.⁶ Payment for professional medical services provided to Medicare beneficiaries by PAs must be paid directly to the employer of the PA.^{7,8}

- ¹ Centers for Medicare and Medicaid Services, Medicare Benefit Policy Manual, Chapter 15: Covered Medical and Other Health Services, §190 Physician Assistant (PA) Services, B. (1) "The services of a PA may be covered under Part B, if all of the following requirements are met: They are the types that are considered physician's services if furnished by a doctor of medicine or osteopathy (MD/DO)." Available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf
- ² 42 C.F.R §410.74.
- ³ Centers for Medicare and Medicaid Services, *Medicare Benefit Policy Manual, Chapter 15: Covered Medical and Other Health Services, §200 Nurse Practitioner (NP) Services, B.* (1) "The services of an NP may be covered under Part B if all of the following conditions are met: They are the types that are considered physician's services if furnished by a doctor of medicine or osteopathy (MD/DO)."
- 4 42 C.F.R. §410.75.
- ⁵ See 42 C.F.R. § 409.10 (b), "Inpatient hospital services does not include...: (4) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act. (5) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act."
- ⁶ Centers for Medicare and Medicaid Services, *Medicare Claims Processing Manual*, Pub. 100-04, Chapter 12 §110.4 (A.), *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf "PA Identification: PAs must have their own "nonphysician practitioner" national provider identification number (NPI) number. This NPI is used for identification purposes only when billing for PA services, because only an appropriate PA employer or, a provider/supplier for whom the PA furnishes services as an independent contractor can bill for PA services."
- ⁷ Centers for Medicare and Medicaid Services, *Medicare Program Integrity Manual*, Chapter 15, §15.4.4.12, *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c15.pdf "Payment for the PA's services may only be made to the PA's employer, not to the PA himself/herself... This also means that the PA does not reassign his or her benefits to the employer, since the employer must receive direct payment anyway."
- ⁸ Centers for Medicare and Medicaid Services, *Medicare Benefit Policy Manual*, Pub. 100-02, Chapter 15, §190(D), available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf. "Employment Relationship: Payment for the services of a PA may be made only to the actual qualified employer of the PA that is eligible to enroll in the Medicare program under existing Medicare provider/supplier categories."

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Payment for professional services provided to Medicare beneficiaries by NPs can be paid directly to the NP or to their employer.^{9, 10}

The consequence of Medicare's payment for services provided by PAs directly to the employer of the PA, and by NPs (who typically reassign their benefits as a condition of their employment), is that physicians relying on the hospital-employed PAs and NPs to provide medical care are unable to bill for or be reimbursed for those services themselves. Only direct employment of the PA and/or NP (under reassignment) constitutes the ability to be paid for services provided by PAs and NPs.

Medicare conditions of payment regulations do require that a PA provide services under the general supervision of a physician, and that an NP provide services in collaboration with a physician, there is no provision. However, for Medicare <u>payment</u> to the physician solely for having provided supervision or collaboration to a PA or NP without the physician also incurring an expense for having provided the service, either by employment or other proper arrangement.

The employment of PAs and NPs for the purposes of "supporting" the physicians, providing medical care that the physicians would otherwise have to provide themselves (if not for the work of those PAs and NPs), can be construed as remuneration in the form of employment services provided by the hospital and/or an inurement for referrals to said hospital. This is a violation of the Anti-Kickback Statute, 13 unless there are proper lease or contractual arrangements in place between the hospital and the physicians to establish an employment arrangement between the physician and PA or NP, because only the employer of the PA (or NP under reassignment) can receive Medicare payment for their professional services. Without proper arrangements, the hospital's employment of the PA/NP can be viewed as a quid pro quo; the hospital bears the burden of the cost of employing a PA/NP to provide the care that the physician or his employee would otherwise have to provide, so that the physician refers patients to that hospital for services.

⁹ See Transmittal 1168, Direct Billing and Payment for Non-Physician Practitioner Services Furnished to Hospital Inpatients and Outpatients, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1168CP.pdf

¹⁰ See also Centers for Medicare and Medicaid Services, Direct Billing and Payment for Non-Physician Practitioner (NPP) Services Furnished to Hospital Inpatients and Outpatients MLN Matters Number MM522, 1-2, available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/ MM5221.pdf

¹¹ Centers for Medicare and Medicaid Services, *Medicare Benefit Policy Manual*, Pub. 100-02, Chapter 15, §190(B) 1. "The services of a PA may be covered under Part B, if all of the following requirements are met: ...They are performed under the general supervision of an MD/DO..." available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf

 $^{^{12}}$ Id., §200(B) 1, "The services of an NP may be covered under Part B if all of the following conditions are met: ... They are performed in collaboration with an MD/DO..."

¹³ 42 U.S.C §1320a-7b.

¹⁴ See 42 C.F.R §1001.952(i).

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Additionally, this scenario would appear to establish the intent requirement in violation of the Anti-Kickback Statute under the "one purpose test," as first illustrated in the landmark case, *United States v. Greber.* "According to *Greber*, "if one purpose of the payment was to induce future referrals, the Medicare statute has been violated"; thus, if "one purpose" of the hospital bearing the financial burden of employing the PAs and NPs is to ensure that the physicians will send/refer their patients insured by Medicare or other federal health programs to that hospital, (thereby increasing patient volume and hospital revenue), then the hospital's act of employing those PAs and NPs can be construed as a bribe or kickback to induce patient referrals, unless there are proper financial arrangements in place. As described, this scenario could also subject the parties to scrutiny under the Physician Self-Referral/Stark Law.¹⁶

It is the Stark compensation arrangement component, defined in the statute as "any arrangement involving any *remuneration* between a physician (or an immediate family member of such physician) and an entity"¹⁷ that can be called into question when a hospital employs PAs and NPs to "support" physicians referring Medicare patients for inpatient and outpatient services (which qualify as designated health services, or DHS). ¹⁸(Emphasis Added.) Remuneration, as defined in the statute, "includes any remuneration, directly or indirectly, overtly or covertly, in cash or in kind." ¹⁹ Thus, employing a PA or NP that the physician would otherwise have to employ, to provide services he would otherwise have to provide, could be considered indirect compensation by the hospital to the physician, and a Stark violation in the form of free labor provided to the physician for his referrals. ²⁰ Any claims submitted to the Medicare program by the physician and/or the hospital, as a result of such "tainted" referrals, could then be subject to false claims liability. ²¹

Physician compensation arrangements are increasingly becoming subject to scrutiny for kickback violations, according to a 2015 Fraud Alert from the OIG.²² The Fraud Alert makes reference to an unnamed case wherein an entity's payment for the physicians' office staff constituted "improper remuneration" by relieving the physicians of the "financial burden they otherwise would have incurred"²³ which might suggest that hospital compliance teams should examine their arrangements with physicians as they relate to the hospital's employment of PAs and NPs providing care to support their referring physicians.

¹⁵ United States v. Greber, 760 F.2d 68, 71-72 (3d Cir. 1985), cert. denied, 474 U.S. 988(1985). See also United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011), United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000) & United States v. Davis, 132 F.3d 1092(5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989).

¹⁶ Id.

¹⁷ 42 U.S.C §1395nn(h)(1)(A).

^{18 42} U.S.C §1395nn(h)(1)(B).

^{19 42} U.S.C §1395nn(h)(6)(k).

²⁰ 42 C.F.R. § 411.354(c)(2).

²¹ 31 U.S.C. §§ 3729 - 3733.

²² Dep't of Health and Human Services, Office of Inspector General, Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability (June 9, 2015), available at https://oig.hhs.gov/compliance/Fraud_Alert_Physician_Compensation_06092015.pdf

Consider the following OIG settlement press releases:

- In 2009, Inova Fairfax Hospital in Virginia allegedly violated the Anti-Kickback Statute and Stark Law for having employed PAs to provide services within the offices of an independent cardiology group, without proper lease or financial arrangements in place. The hospital also failed to bill Medicare Part B for the services provided by the hospital employed PAs. Inova paid more than \$528,158 in civil monetary penalties in the settlement with the OIG.²⁴
- In 2013, University of Louisville Hospital in Kentucky paid \$2,833,408.60 in a False Claims Act settlement with the United States Department of Justice for allegedly including the PA and NP employment costs in the facility cost report calculations, while at the same time allowing the independently contracted provider of emergency services to bill Medicare and collect for services provided by the PAs and NPs.²⁵

Recent case law, *United States of America*, v. *Edward J. Novak*, et al, has emerged in Illinois wherein the hospital administration of Sacred Heart Hospital was indicted (amongst multiple other charges) for the hiring of a PA and NP to "support" a community physician to induce referrals. ²⁶ That case has resulted in multiple convictions and hefty penalties, including jail time for the hospital administrators. In its closing arguments, the government stated that the defendants took the conspiracy to the next level when they began loaning out...– [PAs and NPs] — to doctors free of charge in return for patients, ...calling it "kickbacks on steroids," according to a press account of the trial. ²⁷

There must be appropriate (fair market value) arrangements/service agreements in place for any physician to utilize the PAs or NPs in the care of their patients if they are not employed by the same entity to avoid potential violation of the Anti-Kickback Statute and/or the Physician Self-Referral/Stark Laws.

²⁴ Dep't of Health and Human Services, Office of Inspector General, *Kickback and Physician Self-Referral*, (7-10-2009), available at https://oig.hhs.gov/fraud/enforcement/cmp/kickback.asp#2009. "..., Inova Health Care Services... agreed to pay \$528,158 for allegedly violating the Civil Monetary Penalties Law provisions applicable to kickbacks and physician self-referrals. The OIG alleged that Inova paid remuneration to Arrhythmia Associates (AA) in the form of services provided by certain physician assistants (PA) within the office of AA. Specifically, Inova provided PA services to AA without written contracts in place and failed to bill and collect for those PA services."

²⁵ United States Dep't of Justice, U.S. Attorney's Office, Western District of Kentucky, *Operators Of University Of Louisville Hospital To Pay \$2,833,408.60 To Settle False Medicare Billings* (July 1, 2013) *available at http://www.justice.gov/usao-wdky/pr/operators-university-louisville-hospital-pay-283340860-settle-false-medicare-billings* "...According to the settlement agreement, from January 1, 2006 through December 31, 2010, the salaries and benefits paid to FirstCare PAs and NPs were claimed on UMC cost reports filed with Medicare between 2006-2010. At the same time, University Emergency Medicine Associate (UEMA) physicians generally treated the FirstCare PAs and NPs as their own employees including, to various degrees, billing and collecting from Medicare for their professional services."

²⁶ See generally, Trial Pleading *United States of America, v. Edward J. NOVAK*, et al., U.S. (N.D.III.) No.13 CR 312, (March 18, 2014). 2104 WL 5106618.

²⁷ Lance Duroni, Jury to Weigh Kickback Charges against III. Hospital Execs Law360, Chicago (Mar. 16, 2015, 8:01 PM ET), available at http://www.law360.com/articles/631938/jury-to-weigh-kickback-charges-against-ill-hospital-execs.

EMTALA and PAs/NPs

The Centers for Medicare and Medicaid Services (CMS) website, CMS.gov, provides the following description of the Emergency Medical Treatment & Labor Act:

In 1986, Congress enacted the Emergency Medical Treatment & Labor Act (EMTALA) to ensure public access to emergency services regardless of ability to pay. Section 1867 of the Social Security Act imposes specific obligations on Medicare-participating hospitals that offer emergency services to provide a medical screening examination (MSE) when a request is made for examination or treatment for an emergency medical condition (EMC), including active labor, regardless of an individual's ability to pay. Hospitals are then required to provide stabilizing treatment for patients with EMCs. If a hospital is unable to stabilize a patient within its capability or if the patient requests, an appropriate transfer should be implemented.¹

The regulations for EMTALA fall under the Centers for Medicare and Medicaid Services (CMS) at the Department of Health and Human Services (HHS). The CMS State Operations Manual (SOM) (also called "interpretive guidelines") is written by CMS national staff to guide surveyors who are inspecting hospitals for Medicare and Medicaid participation. The public can access the EMTALA guidelines online in SOM Appendix V.²

The law requires that hospitals provide an appropriate medical screening examination (MSE) to any individual who comes to the facility requesting emergency care. The purpose of the MSE is to determine whether an emergency medical condition exists.

If the clinical staff determines that an emergency medical condition does exist, they must either provide the treatment necessary to stabilize the individual or, if the facility and staff are unable to provide the care needed, the individual may be transferred. The law includes specific criteria that must be met regarding transfers.

Facilities are required to develop policy to ensure compliance with EMTALA regulations, including the following provisions, which should address PAs and NPs, if applicable:

- Medical screening exam
- Certifying false labor
- Emergency call
- Transferring patients

¹ U.S. Department of Health & Human Services, Centers for Medicare and Medicaid Services, *Emergency Medical Treatment & Labor Act (EMTALA)*, https://www.cms.gov/regulations-and-guidance/legislation/emtala/

² State Operations Manual Appendix V – Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases, available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_v_emerg.pdf

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Medical Screening Exam

Summary: The EMTALA law and regulations allow PAs and NPs to conduct medical screening examinations (MSE). A hospital's written policies must specify that PAs/NPs are among the providers qualified to conduct them.

Regulation:

42 CFR §489.24(a)(1)(i):

In the case of a hospital that has an emergency department, if an individual (whether or not eligible for Medicare benefits and regardless of ability to pay) 'comes to the emergency department,' as defined in paragraph (b) of this section, the hospital must provide an appropriate medical screening examination (MSE) within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition exists. The examination must be conducted by an individual(s) who is determined qualified by hospital bylaws or rules and regulations ... (Emphasis added.)

Interpretive Guidelines: §489.24(a)(1)(i):

The MSE must be conducted by an individual(s) who is determined qualified by hospital by-laws or rules and regulations and who meets the requirements of §482.55 concerning emergency services personnel and direction. The designation of the qualified medical personnel (QMP) should be set forth in a document approved by the governing body of the hospital. If the rules and regulations of the hospital are approved by the board of trustees or other governing body, those personnel qualified to perform the medical screening examinations may be set forth in the rules and regulations, or the hospital bylaws. It is not acceptable for the hospital to allow informal personnel appointments that could frequently change.⁴

³ eCFR, §489.24 Special responsibilities of Medicare hospitals in emergency cases, available at <a href="https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr;sid=060daea35afcfbf6b1c6a8bf685d6f87;rgn=div5;view=text;node=42:5.0.1.1.7;idno=42;cc=ecfr#se42.5.489_124

⁴ State Operations Manual Appendix V – Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases, page 41, available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_v_emerg.pdf

Certifying False Labor

Summary: PAs and NPs can certify false labor if they are acting within their scope of practice as defined by the hospital and their individual privileges.

Regulation:

42 CFR §489.24(b) Definitions:

Labor means the process of childbirth beginning with the latent or early phase of labor and continuing through the delivery of the placenta. A woman experiencing contractions is in true labor unless a physician, certified nurse-midwife, **or other qualified medical person acting within his or her scope of practice as defined in hospital medical staff bylaws and State law,** certifies that, after a reasonable time of observation, the woman is in false labor.⁵ (Emphasis added.)

Interpretive Guidelines:

42 CFR §489.24(b):

CMS guidance to surveyors quotes the regulation and provides no additional interpretation.⁶

PAs/NPs Providing Call to the Emergency Department

Summary: The EMTALA CMS Interpretive Guidelines regarding on-call physician responsibilities to the emergency department acknowledge the ability of PAs and NPs ("non-physicians") to provide "further assessment or stabilizing treatment." The guidelines indicate that the <u>on-call physician</u> determines, based on the condition of the patient and the resources available (including the capabilities of the PA/NP on duty), whether to direct the PA/NP to provide the care for the patient in the emergency department.

Regulations:

§489.20 Basic commitments

The provider agrees to the following...

(r) In the case of a hospital as defined in §489.24(b) (including both the transferring and receiving hospitals), to maintain—

⁵ eCFR, §489.24 Special responsibilities of Medicare hospitals in emergency cases, available at https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr;sid=060daea35afcfbf6b1c6a8bf685d6f87;rgn=div5;view=text;node=42:5.0.1.1.7;idno=42;cc=ecfr#se42.5.489">https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr;sid=060daea35afcfbf6b1c6a8bf685d6f87;rgn=div5;view=text;node=42:5.0.1.1.7;idno=42;cc=ecfr#se42.5.489">https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr;sid=060daea35afcfbf6b1c6a8bf685d6f87;rgn=div5;view=text;node=42:5.0.1.1.7;idno=42;cc=ecfr#se42.5.489">https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr;sid=060daea35afcfbf6b1c6a8bf685d6f87;rgn=div5;view=text;node=42:5.0.1.1.7;idno=42;cc=ecfr#se42.5.489">https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr;sid=060daea35afcfbf6b1c6a8bf685d6f87;rgn=div5;view=text;node=42:5.0.1.1.7;idno=42;cc=ecfr#se42.5.489">https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr#se42.5.489">https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr#se42.5.489">https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr#se42.5.489">https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr#se42.5.489">https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr#se42.5.489">https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr#se42.5.489">https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr#se42.5.489">https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr#se42.5.489">https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr#se42.5.489">https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr#se42.5.489">https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr#se42.5.489">https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr#se42.5.489">https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr#se42.5.489">https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr#se42.5.489">https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr#se42.5.489

⁶ State Operations Manual Appendix V – Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_vemerg.pdf page 37.

(2) an on-call list of physicians who are on the hospital's medical staff or who have privileges at the hospital, or who are on the staff or have privileges at another hospital participating in a formal community call plan, in accordance with \$489.24(j)(2)(iii), available to provide treatment necessary after the initial examination to stabilize individuals with emergency medical conditions who are receiving services required under \$489.24 in accordance with the resources available to the hospital; and...⁷

§489.24 Special responsibilities of Medicare hospitals in emergency cases.

- (j)Availability of on-call physicians
- In accordance with the on-call requirements specified in \$489.20(r)(2), a hospital must have written policies and procedures in place—
- (1) To respond to situations in which a particular specialty is not available or the on-call physician cannot respond because of circumstances beyond the physician's control;
- (2) To provide that emergency services are available to meet the needs of individuals with emergency medical conditions if a hospital elects to—
- (i) Permit on-call physicians to schedule elective surgery during the time they are on call;
- (ii) Permit on-call physicians to have simultaneous on-call duties;
- (iii) Participate in a formal community call plan. Notwithstanding participation in a community call plan, hospitals are still required to perform medical screening examinations on individuals who present seeking treatment and to conduct appropriate transfers. The formal community call plan must include the following elements:
- (A) A clear delineation of on-call coverage responsibilities; that is, when each hospital participating in the plan is responsible for on-call coverage.
- (B) A description of the specific geographic area to which the plan applies.
- (C) A signature by an appropriate representative of each hospital participating in the plan.
- (D) Assurances that any local and regional EMS system protocol formally includes information on community-call arrangements.
- (E) A statement specifying that even if an individual arrives at a hospital that is not designated as the on-call hospital, that hospital still has an obligation under §489.24 to provide a medical screening examination and stabilizing treatment within its capability, and that hospitals participating in the community call plan must abide by the regulations under §489.24 governing appropriate transfers.
- (F) An annual assessment of the community call plan by the participating hospitals.8

⁷ eCFR, §489.20 Basic Commitments, available at https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr;sid=060daea35afcf bf6b1c6a8bf685d6f87;rgn=div5;view=text;node=42:5.0.1.1.7;idno=42;cc=ecfr#se42.5.489_120

⁸ eCFR §489.24(j) Availability of On-call Physicians, available at https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr;sid=0 60daea35afcfbf6b1c6a8bf685d6f87;rgn=div5;view=text;node=42:5.0.1.1.7;idno=42;cc=ecfr#se42.5.489 124

Interpretive Guidelines: §489.20(r)(2) and §489.24(j)

If it is permitted under the hospital's policies, an **on-call physician** has the **option** of sending a representative, i.e., directing a licensed non-physician practitioner as his or her representative to appear at the hospital and provide further assessment or stabilizing treatment to an individual. This determination should be based on the individual's medical need and the capabilities of the hospital and the applicable State scope of practice laws, hospital by-laws and rules and regulations. There are some circumstances in which the non-physician practitioner can provide the specialty treatment more expeditiously than the physician on-call. It is important to note, however, that the designated on-call physician is ultimately responsible for providing the necessary services to the individual in the DED, regardless of who makes the in-person appearance. Furthermore, in the event that the treating physician disagrees with the oncall physician's decision to send a representative and requests the actual appearance of the on-call physician, then the on-call physician is required under EMTALA to appear in person. Both the hospital and the on-call physician who fails or refuses to appear in a reasonable period of time may be subject to sanctions for violation of the EMTALA statutory requirements.^{9, 10}(Emphasis added.)

Interpretation: Thus, to meet this EMTALA requirement, the emergency department provider would be required to contact the specialty physician on call regarding the patient in need of specialty care consultation and/or admission, in order that he/she may "direct" the PA/NP as "his/her representative" to assess and provide stabilizing treatment to the patient in the ED.

This interpretation is supported by comments published by CMS in the Federal Register in 2003 regarding PAs providing on-call coverage under the EMTALA rules:

Comment: One commenter stated that some physicians, such as orthopedists, frequently use physician assistants in their practices. The commenter provided a number of examples of how a physician assistant could respond appropriately to a call from an emergency department, participate in the screening of an individual, and either provide the necessary stabilization or post-stabilization services, or arrange for the performance of those services by the physician. The commenter asked us to clarify that, in some instances, physician assistants may appropriately provide on-call coverage, by revising the EMTALA regulations to state that physicians included on a hospital's on-call list may delegate their on-call responsibilities to the physician assistants they supervise, as long as all services provided by the physician assistants are furnished in accordance with State scope of practice laws and with hospital and medical bylaws.

⁹ State Operations Manual Appendix V – Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases, available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_v_emerg.pdf page 31.

U.S. Department of Health and Human Services, Center for Medicaid and State Operations/Survey and Certification Group Memorandum, Inpatient Prospective Payment System (IPPS) 2009 Final Rule Revisions to Emergency Medical Treatment and Labor Act (EMTALA) Regulations, Ref: S&C09-26, March 2009, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter09-26.pdf

Response: We agree that there may be circumstances in which a physician assistant may be the appropriate practitioner to respond to a call from an emergency department or other hospital department that is providing screening or stabilization mandated by EMTALA. However, any decision as to whether to respond in person or direct the physician assistant to respond should be made by the responsible on-call physician, based on the individual's medical needs and the capabilities of the hospital, and would, of course, be appropriate only if it is consistent with applicable State scope of practice laws and hospital bylaws, rules, and regulations. 11, 12 (Emphasis added.)

Transferring Patients

SUMMARY: The EMTALA regulations allow "qualified medical personnel" other than physicians to order the transfer of emergency patients. If a PA/NP is to certify transfer of an unstable patient to another emergency department, the law requires that the PA/NP first consult with a physician before ordering the transfer. Subsequently, the physician must co-sign the order within a timeframe specified in hospital policy.

Regulations: 42 CFR 489.24(e)(ii)(C)

- (e) Restricting transfer until the individual is stabilized—(1) General. If an individual at a hospital has an emergency medical condition that has not been stabilized (as defined in paragraph (b) of this section), the hospital may not transfer the individual unless—
- (i) The transfer is an appropriate transfer (within the meaning of paragraph (e)(2) of this section); and
- (ii)(A) The individual (or a legally responsible person acting on the individual's behalf) requests the transfer, after being informed of the hospital's obligations under this section and of the risk of transfer. The request must be in writing and indicate the reasons for the request as well as indicate that he or she is aware of the risks and benefits of the transfer;
- (B) A physician (within the meaning of section 1861(r)(1) of the Act) has signed a certification that, based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual or, in the case of a woman in labor, to the woman or the unborn child, from being transferred. The certification must contain a summary of the risks and benefits upon which it is based; or

U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services 42 CFR Parts 413, 482, and 489 [CMS-1063-F] RIN 0938-AM34, Medicare Program; Clarifying Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions, https://www.cms.gov/Regulations-and-Guidance/Legislation/EMTALA/Downloads/CMS-1063-F.pdf pages 209-211

¹² Federal Register / Vol. 68, No. 174 / Tuesday, September 9, 2003 / Rules and Regulations, 42 CFR Parts 413, 482, and 489 Medicare Program; Clarifying Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals With Emergency Medical Conditions; Final Rule, https://www.gpo.gov/fdsys/pkg/FR-2003-09-09/pdf/03-22594.pdf#page=2 at 53256 (page 36 of the PDF).

(C) If a physician is not physically present in the emergency department at the time an individual is transferred, a qualified medical person (as determined by the hospital in its by-laws or rules and regulations) has signed a certification described in paragraph (e)(1)(ii)(B) of this section after a physician (as defined in section 1861(r)(1) of the Act) in consultation with the qualified medical person, agrees with the certification and subsequently countersigns the certification. The certification must contain a summary of the risks and benefits upon which it is based. (Emphasis added.)

Interpretive Guidelines: §489.24(e)

The EMTALA regulations at 42 CFR 489.24(b) define "transfer" as "...the movement (including the discharge) of an individual outside a hospital's facilities at the direction of any person employed by (or affiliated or associated, directly or indirectly, with) the hospital, but does not include such a movement of an individual who (i) has been declared dead, or (ii) leaves the facility without the permission of any such person."

The requirements in 42 CFR 489.24(e) apply to transfers to another hospital.

Transfer with a Physician Certification

Alternatively, a transfer may be made when a physician certifies that the expected benefits of the transfer outweigh the risks. Specifically, a physician must certify that the medical benefits to the individual with the EMC that could reasonably be expected from provision of appropriate treatment at another hospital outweigh the increased risks that result from being transferred. In the case of a pregnant woman in labor, the physician must certify that the expected benefits outweigh the risk to both the pregnant woman and the unborn child. Under certain circumstances, qualified medical personnel other than a physician may sign the certification. A qualified medical person (QMP) may sign the certification of benefits versus risks of a transfer only after consultation with a physician who agrees with the transfer. The physician must subsequently countersign the certification. The physician's countersignature must be obtained within the established timeframe according to hospital policies and procedures. Hospital by-laws or rules or regulations must specify the criteria and process for granting medical staff privileges to OMPs, and, in accordance with the hospital or CAH Conditions of Participation, each individual QMP must be appropriately privileged.

The date and time of the physician (or the QMP) certification should closely match the date and time of the transfer.

Section 1861(r)(i) of the Act defines **physicians** as:

¹³ eCFR https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr;sid=060daea35afcfbf6b1c6a8bf685d6f87;rgn=div5;view=text;node=42:5.0.1.1.7;idno=42;cc=ecfr#se42.5.489 124

A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action. (This provision is not to be construed to limit the authority of a doctor or medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State's regulatory mechanism). (Emphasis added.)

Women in Labor

Regardless of practices within a state, a woman in labor may be transferred only if she or her representative requests the transfer or if a physician **or other qualified medical personnel signs a certification that the benefits outweigh the risks.** If the hospital does not provide obstetrical services, the benefits of a transfer may outweigh the risks. A hospital cannot cite State law or practice as the basis for transfer. ¹⁵ (Emphasis added.)

General References:

- United States Code at Title 42 USC §1867, Chapter 7 (Social Security), subchapter XXVIII, Part D, Sec.1395cc, <u>Medicare Provider Agreements</u>, and Sec.1395dd, <u>Examination and treatment for emergency medical conditions and women in labor</u>
- Code of Federal Regulations, Title 42,\$489.20, <u>Provider Agreements: Basic Commitments</u> and \$489.24, et seq., <u>EMTALA on-call responsibilities</u>
- CMS State Operations Manual, Interpretive Guidelines, Appendix V, Responsibilities of Medicare Participating Hospitals in Emergency Cases (EMATLA)

¹⁴ State Operations Manual Appendix V – Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases, available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_v_emerg.pdf pages 60-61

¹⁵ State Operations Manual Appendix V – Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases, available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_v_emerg.pdf p.61

Medical Record Documentation

Compliance Consideration: Medical Record Documentation and Authentication

Medical record authentication is a compliance concern, with relevant standards found in Medicare payment rules,¹ the Medicare Conditions of Participation,² The Joint Commission standards,³ and the HIPAA Security Rule.⁴

Compliance Consideration: Cloning/Copy-Pasting Notes in the EHR

Medicare payment policy is found in the Program Integrity Manual:

3.3.2 - Medical Review Guidance

This section applies to MACs, CERT, Recovery Auditors, and ZPICs, as indicated. This section describes the requirements that MACs, CERT, Recovery Auditors, and ZPICs shall follow when reviewing submitted documentation. Additional requirements for ZPICs are located in PIM chapter 4. When ZPIC staff is performing benefit integrity reviews, their focus is different than that of MACs, CERT, and Recovery Auditors. For example, ZPIC staff looks for some of the following situations when reviewing documentation:

Possible falsification or other evidence of alterations including, but not limited to: obliterated sections; missing pages, inserted pages, white out; and excessive late entries;

Evidence that the service billed for was actually provided; or,

Patterns and trends that may indicate potential fraud.⁵

RC.01.02.01: Entries in the medical record are authenticated.

EP 3.The author of each medical record entry is identified in the medical record.

EP 4.Entries in the medical record are authenticated by the author. Information introduced into the medical record through transcription or dictation is authenticated by the author

¹ MLN Matters® Number: MM6698 Revised /Signature Guidelines for Medical Review Purposes http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6698.pdf
"For medical review purposes, Medicare requires that services provided/ordered be authenticated by the author. The method used must be a hand written or an electronic signature. Stamp signatures are not acceptable." Thus, transcribed notes should be directed to the PA/APRN who dictated the note for authentication. The note can then be forwarded, if necessary for review and signature.

² §482.24(b) Standard: Form and Retention of Record:

[&]quot;The hospital must have a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries."

[&]quot;The medical record system must correctly identify the author of every medical record entry and must protect the security of all medical record entries."

³ Joint Commission Accreditation Manual for Hospitals,

⁴ HIPAA Security Rules: https://www.hhs.gov/hipaa/for-professionals/security/index.html

⁵ Department of Health and Human Services, Centers for Medicare and Medicaid Services, Program Integrity Manual, Chapter 3, *Verifying Potential Errors and Taking Corrective Actions§3.3.2* http://www.cms.gov/Regulations-and-Guidance/Manuals/Downloads/pim83c03.pdf

OIG report: "CMS and its Contractors Have Adopted few Program Integrity Practices to Address Vulnerabilities in EHRs"

Objective

To describe how the Centers for Medicare & Medicaid Services (CMS) and its contractors implemented program integrity practices in light of electronic health records (EHRs) adoption.

Background

Electronic Health Records EHRs replace traditional paper medical records with computerized recordkeeping to document and store patient health information. EHRs may include patient demographics, progress notes, medications, medical history, and clinical test results from any healthcare encounter.

EHRs may create new vulnerabilities, requiring CMS and its contractors to revise their approaches to protect against fraud and abuse. For example, clues within the progress notes, handwriting styles, and other attributes that help corroborate the authenticity of paper medical records are largely absent in EHRs. Further, tracing authorship and documentation in an EHR may not be as straightforward as tracing in a paper record. Healthcare providers can use EHR software features that may mask true authorship of the medical record and distort information in the record to inflate healthcare claims.

Below we describe two examples of EHR documentation practices that could be used to commit fraud.

Copy-pasting. Copy-pasting, also known as cloning, enables users to select information from one source and replicate it in another location. When doctors, nurses, or other clinicians copy-paste information but fail to update it or ensure accuracy, inaccurate information may enter the patient's medical record and inappropriate charges may be billed to patients and third-party healthcare payers. Furthermore, inappropriate copypasting could facilitate attempts to inflate claims and duplicate or create fraudulent claims.⁶

AHIMA: Integrity of the Healthcare Record — Best Practices for EHR Documentation

Healthcare Fraud and Abuse

Healthcare fraud is defined as an "intentional deception or misrepresentation that the individual or entity makes knowing that the misrepresentation could result in some unauthorized benefit to the individual, to the entity or to some other party." The intentional fabrication of medical records in order to improve reimbursement may be considered fraudulent. This fabrication could result from overuse of "copy-paste" functionalities or misuse of templates originally designed for documentation efficiency.

⁶ Department of Health and Human Services, Office of Inspector General. CMS and its Contractors Have Adopted Few Program Integrity Practices to Address Vulnerabilities in EHRS, Daniel R. Levinson, Inspector General. January 2014 OEI-01-11-00571 https://oig.hhs.gov/oei/reports/oei-01-11-00571.pdf

Healthcare abuse describes incidents or practices which are not usually fraudulent but are not consistent with accepted medical or business practices that may result in unnecessary costs to payers. These unintentional practices may involve repeated billing and coding errors that over time may be considered fraudulent if patterns of continued practice are found upon external review.

When misrepresentation occurs — whether it is intentional or unintentional — the staff member that has responsibility for ensuring an accurate claim has the obligation to proactively identify and prevent fraud. All providers involved in the patient's care must be held accountable to ensure the integrity of the documentation is compliant with existing law and that the level of service reported meets all payer billing, coding, and documentation requirements. According to the Medicare Claims Processing Manual, "Medical necessity is the overarching criterion for reimbursement... and the volume of documentation should not be the primary influence upon which a specific level of service is billed."

CMS: Electronic Health Records Provider Fact Sheet

4. Cloning — This practice involves cutting and pasting previously recorded information from a prior note into a new note, and it is a growing problem in healthcare. For example, features like auto-fill and auto-prompts can facilitate and improve provider documentation, but they can also be misused. The medical record must contain documentation showing the differences and the needs of the patient for each visit or encounter. Simply changing the date on the EHR without reflecting what occurred during the actual visit is not acceptable. Using electronic signatures or a personal identification number (PIN) may help deter some of the possible fraud, waste, and abuse that can occur with increased use of EHRs. In its 2013 Work Plan, the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG) indicated that due to the growing problem of cloning, its staff would be paying close attention to EHR cloning.⁸

The OlG report cites Not All Recommended Safeguards Have Been Implemented in Hospital EHR Technology OEI-01-11-00570 and a report prepared for ONC, Recommended Requirements for Enhancing Data Quality in Electronic Health Record Systems. Note the recommendations for scrutiny of the copy-paste function and the ability to identify the date and author of the documentation carried forward.

From AHIMA:

Article citation:

Dimick, Chris. "Documentation Bad Habits: Shortcuts in Electronic Records Pose Risk." *Journal of AHIMA* 79, no.6 (June 2008): 40-43.

⁷ AHIMA. "Integrity of the Healthcare Record: Best Practices for EHR Documentation." *Journal of AHIMA* 84, no.8 (August 2013): 58-62 http://library.ahima.org/doc?oid=300257#.WFLMpLlrKvE

⁸ Department of Health and Human Services, Centers for Medicare and Medicaid Services, *Electronic Health Records Provider Fact Sheet*, December 2014, https://www.cms.gov/Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/ehr-providerfactsheet.pdf

From Medical Economics:

Terry, K. Avoiding EHR Note Cloning While Maintaining Efficiency, *Medical Economics*http://medicaleconomics.modernmedicine.com/medical-economics/content/tags/cloning/avoiding-ehr-note-cloning-while-maintainingefficiency?page=full Accessed 10 April 2017

DOJ: Settlement (in part) for "Cloned Medical Records"

Louisville Based MD2U, a Regional Provider of Home-Based Care, and Its Principal Owners Admit to Violating the Federal False Claims Act and Being Liable for Millions: Knowingly Presented False Claims and Altered Records to Get False Claims Paid Will Pay Millions to Settle Allegations.

MD2U also utilized an electronic medical records (EMR) system that permitted the NPPs to easily electronically cut, copy and paste medical notes from prior visits. The ability to migrate notes from visits that occurred weeks, months, or even years prior to the current patient encounter created the illusion that MD2U's NPPs were performing a significant amount of work during their patient encounters when, in fact, they were not. If the documentation was deficient to bill the highest level code, MD2U would direct NPPs to go back and change the medical record – after the encounter had occurred – to falsely show that more work was performed during the visit in order to support the highest level billing.⁹

⁹ United States v. MD2U Holding Company et al., Case No. 3:16-cv-00440-GNS, USAO - Kentucky, Western, Updated July 7, 2016, https://www.justice.gov/opa/pr/louisville-based-md2u-regional-provider-home-based-care-and-its-principal-owners-admit



Clinical Policy Considerations

27

Informed Consent/Surgical Site Marking

Introduction

There are multiple regulatory requirements governing facilities that must be considered when creating policy. For hospitals, those requirements may include (but are not limited to):

- State law (PA Practice Act, Medical Practice Act, NP Practice Act, etc.).
- State regulations promulgated by state agencies (such as the Department of Public Health/Public Health Code).
- Medicare's Conditions of Participation (CoPs) for Hospitals. These regulations apply to all hospitals that participate in the Medicare program/care for Medicare beneficiaries. The consequence of noncompliance can be enormous; citations can impact Medicare funding and, in extreme jeopardy cases, can close the facility entirely.
- Accreditation Standards from industry regulators such as The Joint Commission (TJC), DNV-GL (DNV), HFAP, and URAC. TJC has approximately 80 percent of the hospital accreditation market, accrediting "3,300+ hospitals" with DNV accrediting "approximately 500" facilities according to their respective websites. Policy writers must know with which accrediting bodies' standards their organization must comply.

The Medicare CoPs, TJC, and DNV-GL standards contain requirements that must be met for "informed consent," including that the facility must have policy.

The first order of business is to review the organization's current policy, which typically is available via the hospital intranet in the "policies and procedures" manual.

The entire breadth of the issue involves not only regulatory considerations, but also malpractice/risk mitigation strategies as well as ethical and moral duties to the patient.

Some relevant regulations pertinent to the question "are PAs/NPs allowed?" include:

Medicare's Conditions of Participation¹

A-0466

[All records must document the following, as appropriate:]

\$482.24(c)(4)(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.

Interpretive Guidelines §482.24(c)(4)(v)

Informed consent is discussed in three locations in the CMS Hospital CoPs. See also the guidelines for 42 CFR 482.13(b)(2) pertaining to patients' rights, and the guidelines for 42 CFR 482.51(b)(2), pertaining to surgical services. The medical record must contain a

¹ State Operations Manual Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals (Rev. 151, 11-20-15), available at http://www.cms.gov/manuals/downloads/som107ap_a_hospitals.pdf There are multiple sections pertaining to "informed decisions" and "informed consent"; while certain standards have been highlighted here to provide guidance for this topic, all standards must be met.

document recording the patient's informed consent for those procedures and treatments that have been specified as requiring informed consent. Medical staff policies should address which procedures and treatments require written informed consent. There may also be applicable Federal or State law requiring informed consent. The informed consent form contained in the medical record should provide evidence that it was properly executed.²

A-0955

482.51(b)(2) A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.

The guidance for A-0955 includes the following paragraph:

Hospitals must assure that the practitioner(s) responsible for the surgery obtain informed consent from patients in a manner consistent with the hospital's policies governing the informed consent process. (Emphasis added.)

And

"Surgical Informed Consent Policy

The hospital's surgical informed consent policy should describe the following:

- Who may obtain the patient's informed consent;
- Which procedures require informed consent..."³

DNV-GL NIAHO® Accreditation Standards — Acute Care4

Standards for Informed Consent largely mirror the language found in the Medicare CoPs:

"A properly executed informed consent form contains at least the following:

- Name of patient, and when appropriate, patient's legal guardian;
- Name of hospital;

² Id., pages 283-284.

³ *Id.*, p.464.

⁴ Only applies to DNV-GL NIAHO® accredited organizations. DNV-GL NIAHO® Accreditation Standards - Acute Care are open access and free to download after entering some minimal information at http://dnvglhealthcare.com/standards According to the website, "This NIAHO® Accreditation Requirements, Interpretive Guidelines and Surveyor Guidance document is based upon the Centers for Medicare and Medicaid Services Conditions of Participation 42 CFR § 482 and State Operations Manual Regulations and Interpretive Guidelines for Hospitals." Standards for Informed Consent start on page 150 of the PDF.

- Name of specific procedure(s) or medical treatment);
- Name of the responsible practitioner who is performing the procedure(s) or administering the medical treatment;
- Signature of patient or legal representative;
- Date and time consent form is signed by the patient or the patient's legal representative;
- Statement that procedure/treatment including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's legal representative; (Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity. Hospitals are free to delegate to the responsible practitioner, who uses the available clinical evidence as informed by the practitioner's professional judgment, the determination of which material risks, benefits, and alternatives will be discussed with the patient.)
- Name of person who explained the procedure to the patient or guardian."5

The Joint Commission Standards⁶

The Joint Commission standards are proprietary and available only to Joint Commission-accredited organization clients. Organizations pay a significant fee for accreditation and the resources associated with survey preparation and compliance. The facility's accreditation/quality and risk department is typically tasked with the Joint Commission survey preparation and therefore has access to the manuals and standards.

The **Patient Rights (RI) and Record of Care (RC)** standards regarding consent contain relevant provisions for informed consent, including RI.01.03.01, the requirement for having an informed consent policy. **RI.01.03.01** contains the following rationale:

Obtaining informed consent presents an opportunity to establish a mutual understanding between the patient and the licensed independent practitioner or **other licensed practitioners with privileges** about the care, treatment, and services that the patient will receive. Informed consent is not merely a signed document. It is a process that considers patient needs and preferences, compliance with law and regulation, and patient education. Utilizing the informed consent process helps the patient to participate fully in decisions about his or her care, treatment, and services.⁷

⁵ *Id.*, p.151.

⁶ Only applies to Joint Commission accredited organizations.

⁷ The Joint Commission E-dition Comprehensive Accreditation and Certification Manual, Hospital Program, © 2017 The Joint Commission, © 2017 Joint Commission Resources. E-dition is a registered trademark of The Joint Commission

The Joint Commission's National Patient Safety Goal, known as the "Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery" has been a key driver for how hospitals have defined their pre-procedure processes and policies, which impacts the informed consent process to an extent.

The goal of this set of standards it the elimination of wrong-site, wrong-procedure, and wrong-person surgery. The standards require verification of the procedure to be performed, surgical site marking, and the "time out." The standards contain provisions that must be incorporated into policy. While this standard does not address who must obtain the consent, the consent is part of the procedure verification process and the surgical site marking activity. The procedure described on the consent form must correlate with the site marking (for example, left ankle/mark on left ankle) and vice versa. Thus, in many facilities, the consent and surgical site marking are performed in tandem **by the responsible practitioner.**

Example: "You consent to XXX procedure on your left ankle-sign here on this form. We are going to operate here."-Points to left ankle.—"Is that correct?" Responsible practitioner marks the spot on the patient's left ankle after patient confirms the site is correct.

Surgical Site Marking

There are provisions in the standards for PAs and APRNs to participate in surgical site marking. The introduction to Standard UP.01.02.01 states, in part:

Responsibility for marking the procedure site is a hotly debated topic. One position is that since the licensed independent practitioner is accountable for the procedure, he or she should mark the site. Another position is that other individuals should be able to mark the site in the interests of work flow and efficiency.

There is no evidence that patient safety is affected by the job function of the individual who marks the site. The incidence of wrong-site surgery is low enough that it is unlikely that valid data on this subject will ever be available. Furthermore, there is no clear consensus in the field on who should mark the site. Rather than remaining silent on the subject of site marking, The Joint Commission sought a solution that supports the purpose of the site mark. The mark is a communication tool about the patient for members of the team. Therefore, the individual who knows the most about the patient should mark the site. **In most cases, that will be the person performing the procedure.** (Emphasis added.)

Recognizing the complexities of the work processes supporting invasive procedures, The Joint Commission believes that delegation of site marking to another individual is acceptable in limited situations as long as the individual is familiar with the patient and involved in the procedure. These include:

- Individuals who are permitted through a postgraduate education program to participate in the procedure.

⁸ National Patient Safety Goals Effective January 2017: Hospital Accreditation Program. The National Patient Safety Goals are posted on the Joint Commission's website as open access, available at https://www.jointcommission.org/assets/1/6/NPSG_Chapter_HAP_Jan2017.pdf See standards UP.01.01.01-UP.01.03.01, pages 14-17.

- A licensed individual who performs duties requiring collaborative or supervisory agreements with a licensed independent practitioner. These individuals include advanced practice registered nurses (APRNs) and physician assistants (PAs).

The licensed independent practitioner remains fully accountable for all aspects of the procedure even when site marking is delegated." (Emphasis added.)

Standard UP.01.02.01, Element of Performance 3, (a requirement upon which the hospital will be scored by the surveyor during the site visit), states the following:

- 3. The procedure site is marked by a licensed independent practitioner who is ultimately accountable for the procedure and will be present when the procedure is performed. In limited circumstances, the licensed independent practitioner may delegate site marking to an individual who is permitted by the organization to participate in the procedure and has the following qualifications:
- An individual in a medical postgraduate education program who is being supervised by the licensed independent practitioner performing the procedure; who is familiar with the patient; and who will be present when the procedure is performed
- A licensed individual who performs duties requiring a collaborative agreement or supervisory agreement with the licensed independent practitioner performing the procedure (that is, an advanced practice registered nurse [APRN] or physician assistant [PA]); who is familiar with the patient; and who will be present when the procedure is performed.

Note: The hospital's leaders define the limited circumstances (if any) in which site marking may be delegated to an individual meeting these qualifications. (Emphasis added.)

Conclusion

Because pre-procedure verification is reliant, in part, on the procedure described/indicated on the consent form, and the surgical site marking must be performed by someone who will be present when the procedure is performed and who is ultimately accountable, facility policy will often require the consent to be obtained/verified at the time of the surgical site marking by the practitioner performing the procedure. Informed consent is not solely a signature on a form, but an entire process to ensure that the patient is fully informed and that the patient's healthcare team is also informed to avoid wrong person/wrong site surgery.

Malpractice carriers should also be consulted for guidance on obtaining proper informed consent.

The content above is not all-encompassing, but is meant to provide some direction on this issue as organizations update their policies to include PAs and NPs.

⁹ *Id*, page 16.

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Policy Considerations for PAs and NPs in Surgery

Introduction

PAs and NPs (to a lesser extent) are increasingly practicing in surgical specialties and subspecialties. Organizations must develop policy regarding the provision of surgical services to meet many regulatory requirements in the facility setting. The following topics are by no means exhaustive or all-encompassing, but highlight some key considerations pertinent to PAs and NPs providing surgical services:

- First assistant/surgical privileges
- Teaching hospitals and "qualified residents"
- Surgeon documentation when a PA/NP provides first assist services
- "Concurrent"/overlapping or simultaneous surgeries

First Assistant/Surgical Privileges

Qualifications

Organizations have been challenged when determining the minimal qualifications for surgical privileges for PAs and NPs, particularly when considering new graduates. The credentialing professionals expect physician residency case logs and competency attestations from residency program chairs in order to grant surgical privileges for physicians. As PAs/NPs seek similar privileges, the credentialing staff are understandably looking for similar documentation from the programs, sometimes even to the point where they are expecting a postgraduate surgical residency.

The Accreditation Review Commission on Education for the Physician Assistant (ARC-PA) is the accrediting agency that defines the standards for PA education. PAs are trained in the medical model and have a common educational blueprint across the various medical competencies, including exposure to general surgery, a *required* supervised clinical experience rotation. Every accredited PA program must, at minimum, meet the following standards:

B3.03 Supervised clinical practice experiences must provide sufficient patient exposure to allow each student to meet program expectations and acquire the competencies needed for entry into clinical PA practice with patients seeking:

- a) medical care across the life span to include, infants, children, adolescents, adults, and the elderly,
- b) women's health (to include prenatal and gynecologic care),
- c) care for conditions requiring surgical management, including preoperative, intra-operative, post-operative care and
- d) care for behavioral and mental health conditions.

¹ Accreditation Review Commission on Education for the Physician Assistant http://www.arc-pa.org/accreditation/standards-of-accreditation/

B3.04 Supervised clinical practice experiences *must* occur in the following settings: ...

- a) outpatient,
- b) emergency department,
- c) inpatient and
- d) operating room.2

B3.07 *Supervised clinical practice* experiences should occur with preceptors practicing in the following disciplines: ...

- a) family medicine,
- b) internal medicine,
- c) general surgery,
- d) pediatrics,
- e) ob/gyn and
- f) behavioral and mental health care.³ (Emphasis added.)

Thus, most PAs have completed training in the basic competencies of sterile technique, surgical care, operating room protocols, and suturing and surgical care; functioning as first assist in surgery is part and parcel of training for most programs; while some programs have more general surgical exposure than others, students may choose elective rotations that afford more than the basic exposure in general surgery.

Nurse practitioner programs generally do not include surgical training and NP certifications are generally primary care focused. The NP scope of practice has been defined by the National Council of State Boards of Nursing APRN Advisory Committee in the Consensus Model for APRN Regulation,⁴ which makes no mention of surgical exposure for the NP educational path, other than that of the CRNA. The APRN Consensus Model does address scope in depth, specifically about population focus in education, which then leads to their certification with a population focus. As a result, in most instances, nurse practitioners are required to attend an RNFA program in order to be credentialed for first assisting in surgery.

Medicare Conditions of Participation: Surgical Privileges

Medicare's Conditions of Participation for Hospitals and correlating *Interpretive Guidelines* address the provision of surgical care.⁵ While no standards should be considered in isolation, and all standards must be met, the following standard provides guidance regarding policy for

² Accreditation Standards for Physician Assistant Educationã Fourth Edition, http://www.arc-pa.org/wp-content/uploads/2016/10/Standards-4th-Ed-March-2016.pdf page 20.

³ *Id.*, page 21.

⁴ Consensus Model for APRN Regulation: Licensure, Accreditation, Certification & Education July 7, 2008, National Council of State Boards of Nursing, https://www.ncsbn.org/Consensus_Model_Report.pdf

State Operations Manual Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf

physician presence and/or the ability of the PA/NP to perform certain tasks or procedures without the surgeon in the operating room:

A-0945

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.51(a)(4) Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

Interpretive Guidelines §482.51(a)(4)

The hospital must specify the surgical privileges for each practitioner that performs surgical tasks. This would include practitioners such as MD/DO, dentists, oral surgeons, podiatrists, RN first assistants, nurse practitioners, surgical physician assistants, surgical technicians, etc. When a practitioner may perform certain surgical procedures under supervision, the specific tasks/procedures and the degree of supervision (to include whether or not the supervising practitioner is physically present in the same OR, in line of sight of the practitioner being supervised be delineated in that practitioner's surgical privileges and included on the surgical roster. (Emphasis added.)

Teaching Hospitals and "Qualified Residents"

Medicare payment rules require that PAs and NPs should not be utilized as a first assistant if a "qualified resident" is available in teaching hospitals. The surgeon will be required to certify/ attest that "no qualified resident was available" with the following statement in the operative report:

I understand that section 1842(b)(7)(D) of the Social Security Act generally prohibits Medicare physician fee schedule payment for the services of assistants at surgery in teaching hospitals when qualified residents are available to furnish such services. I certify that the services for which payment is claimed were medically necessary and that no qualified resident was available to perform the services. I further understand that these services are subject to post-payment review by the Medicare carrier.⁸

CMS has provided insight on what might constitute a "qualified resident" with this posting from 2003:9

⁶ *Id.*, p.457.

⁷ Medicare Claims Processing Manual, Chapter 12 - Physicians/Nonphysician Practitioners, §100.1.7 - Assistants at Surgery in Teaching Hospitals. *Available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf see page 165, accessed April 14, 2017.

⁸ DEP'T OF HEALTH AND HUMAN SERVICES, Centers for Medicare & Medicaid Services, CMS Manual System, Medicare Carriers Manual Part 3-Claims Process, TRANSMITTAL 1780, Change Request 2290, November 22, 2002, Supervising physicians in teaching settings, <a href="https://www.cms.gov/Regulations-and-Guidance/Gui

⁹ CMS.gov, Physician Regulatory Issues Team (PRIT), First assistant at a hospital with a surgical training program billing. 12-01-03 Available at https://www.cms.gov/Outreach-and-Education/Outreach/PRIT/Past-PRIT-Issues-ltems/CMS062962.html accessed April 14, 2017.

Issue: When is it appropriate to bill Medicare for a first assistant at a hospital with a surgical training program?

Teaching physicians are concerned about the lack of clarity about when they can bill for a surgical first assistant versus when they should have a surgical resident first assist.

...Medicare doesn't pay for assistants at surgery services furnished in a teaching hospital, which has a training program related to the required medical specialty, and has a qualified resident available, except if the physician certifies that a qualified resident was not available, or if the primary physician has a policy of never involving residents in surgery, or if exceptional medical circumstances exist. (Emphasis added.)

CMS provides the following glossary definition of "intern or resident" in the *Teaching Physicians* Fact Sheet:

An individual who participates in an approved GME Program or a physician who is not in an approved GME Program but who is authorized to practice only in a hospital setting (for example, has a temporary or restricted license or is an unlicensed graduate of a foreign medical school). For DGME and IME payment purposes, a resident means an intern, resident, or fellow who is formally accepted, enrolled, and participating in an approved medical residency program including programs in osteopathic medicine, dentistry, and podiatry as required to become certified by the appropriate specialty board. ¹⁰

Some academic medical centers and affiliated facilities serve many teaching programs with a variety of residents and "fellows," including some which may not be accredited or GME funded programs. It is imperative that the organization determines which residents are considered "qualified" for the purposes of meeting the rules for assistants at surgery in teaching hospitals.

Enforcement Activity/Emerging Case Law

A recent whistleblower case has emerged that bears watching, which alleges that the "teaching hospital allowed surgeons to bill Medicare and Medicaid for surgeries performed with assistant surgeons and physician assistants when qualified residents were available to help, in violation of the False Claims Act."^{11,12}

¹⁰ Department of Health and Human Services, Centers for Medicare & Medicaid Services, *Guidelines for Teaching Physicians, Interns, and Residents, Medicare Learning Network ICN 006347 February 2015, available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Teaching-Physicians-Fact-Sheet-ICN006437.pdf See Glossary page 9.*

¹¹ Kass, D., "Hospital Lied About Resident Availability, Says FCA Suit", Law 360, August 11, 2016. Available at http://www.law360.com/articles/827368/hospital-lied-about-resident-availability-says-fca-suit accessed April 14, 2017.

[&]quot;He provides several examples of surgeries involving Medicare beneficiaries when surgeons or physician assistants were brought in when qualified residents were available. The surgeons would then bill Medicare, falsely certifying with the modifier that residents couldn't be used, the complaint states. One physician, co-defendant William M. Hopkins, would use his daughter, a physician assistant, regularly when residents were available, the suit alleges."

¹² United States of America, et al. v. Advocate Health and Hospitals Corp., et al., case number 1:13-cv-01826, in the U.S. District Court for the Northern District of Illinois.

Surgeon Documentation When a PA/NP Provides First-assist Services

Documentation for the surgical procedure/operative report is the responsibility of the surgeon, who must establish not only the medical necessity for the procedure performed (and billed to the Medicare program), but also for the first assistant's participation in the procedure. The first assistant should not be dictating the operative note; as a medically necessary, active participant in the case, the PA/NP is **not** functioning as a scribe and thus cannot serve as a "living recorder" for the case.

Recently, National Government Services, the Medicare Administrative Contractor for the entire Northeast and several upper Midwest states, posted the following guidance regarding documentation for assistant at surgery billing:¹³

Assistant at surgery billing documentation reminder

Claims for assistant at surgery with a zero (0) indicator in the MPFSDB must have information to support and identify the assistant and also support the medical necessity of his/her assistance with the procedure. Listing an assistant on the operative report and making references to "we" and "us" **are not** sufficient evidence to support medical necessity. There must be a medically valid reason in the operative report for the assistant at surgery for the claim to be paid. If the claim is denied for medical necessity, the appeals process must be followed to submit additional supporting documentation. Claims billed for an assistant at surgery that do not have the assistant listed in the operative report will be denied.

National Government Services, Policy Education Topics, Assistant at Surgery Documentation Requirements, available at https://www.ngsmedicare.com/ngs/portal/ngsmedicare/newngs/home-lob/pages/policy-education/documentation/assistant%20at%20surgery%20billing%20documentation%20reminder/!ut/p/a1/xVNdk9ogFP0r6YNPOxkwoMZHEm2S-pHVrtXkxUFgs9SEZBJ0x_76Erud6sN2vzpTXuBcDpfDuVyQgg1IFT3KjGpZKpq30O1vMYnG3a4PJ7EbQkgml4LJPEABRmANUpA29ChYWe6laBHLBa3_w0U4iOL5eUPpSj-ARGVNIbhktDanlBZKK_HYgRfhM67KXLLT79kS_MD0sixdVpl1HchLdijM6X0OA2nTyEZTpS2qreZQZ6I-WTuZ51Jl1hXXqkUhFRd1q6pikoOkPxR8N-TQvseC2hghZA-x69qDHucuY7AvhrxlT2MPJLe01pZnzEmM0fCZQeCrvLuioNiFBH_2RqPFLQo854nwlysSo2Hw7CU-BF_f-MYXEjq_Eq792XaxGi8N-6L4BI0W38Cn4pvVpXH_VFH3vyuCva4pm4-jAQ5DJ74bfNT0YBWNzR09yWq6gk4U4Dcn_PLS3zN_16In_iwzaalsKW6L8HmqkvA5jOdtTZmeqfTzbcFqIr9MnBRYW_g9151_HFHSFhs5zNCxM6FqA1Nwz359BNfJawo/dl5/d5/L2dBISEvZ0FBIS9nQSEh/?clearcookie=&savecookie=®ION=&LOB=Part%20B_accessed_April_13, 2017.

"Concurrent"/Overlapping or Simultaneous Surgeries

The Issue

Recent press coverage^{14, 15, 16} and resulting public controversy has heightened the scrutiny of "concurrent surgery." This scrutiny spurred the American College of Surgeons (ACS) to update their *Statements on Principles*¹⁷ last year. While not regulation or law, they are viewed as clinical guidelines from the professional society representing surgeons. Thus, CMS and accrediting bodies hold them in fairly high regard, and they serve as a valid rationale upon which to base organizational policies.

Also in response to the controversy, the Senate Finance Committee held a hearing on Concurrent and Overlapping Surgery in December 2016.¹⁸ The report addresses a host of regulatory considerations on the issue, including the Medicare Conditions of Participation and accreditation standards; the report is well cited and could serve as a compliance roadmap for drafting policy.

As stated earlier in the discussion of PA/NP surgical privileges, the Medicare CoP

At the time, Paley was supervising a surgical team that "routinely performed simultaneous surgical procedures on separate patients in multiple surgical suites," the complaint says.

"The state claims Paley successfully took out the rod then handed the boy off to physician assistant to prep the child for the insertion of a device, about the size of a paper clip and shaped like an 8, commonly used to treat an abnormality.

Paley meanwhile "rotated to a different operating suite" to tend to another patient, the complaint states. The physician assistant prepped the inner side of the boy's left knee instead of the top part, the state said. The assistant then passed the boy off to a surgical fellow "who had just rotated in from a third, unrelated surgical procedure, in a third simultaneously operating surgical suite," according to the Health Department complaint.

The surgical fellow inserted the so-called "8-plate" on the wrong side of the boy's left knee." State regulators assert that Paley "is responsible and legally liable" for the care given to the boy.

In a written response filed with the Health Department, Paley said only one other procedure — not several — was taking place at the time of the surgery and that he was in the room when a physician assistant removed the rod from the boy's leg.

Paley acknowledged that the physician assistant inserted guide wires for the 8-plate on the wrong side of the boy's left knee, but said the whole leg had been prepped earlier and he had instructed the surgical fellow to insert the device on the top or "lateral" side of the knee.

Paley denied he was legally responsible for the actions of the physician assistant and said "he did not perform, attempt to perform, or prepare the patient for a wrong-site procedure."

¹⁴ Jenn Abelson, Jonathan Saltzman, Liz Kowalczyk, Scott Allen, "Clash in the Name of Care: A Spotlight Team Report", Boston Globe, October 25, 2015. *Available at https://apps.bostonglobe.com/spotlight/clash-in-the-name-of-care/story/?p1=Clash_Landing_to-story_accessed April 14, 2017.*

¹⁵ Jenn Abelson, Jonathan Saltzman, "Surgeons must tell patients of double-booked surgeries, new guidelines say", Boston Globe, April 13, 2016, available at http://www.bostonglobe.com/metro/2016/04/13/surgery/Jn7Lb0Hq3VUGeZGBgjiw0M/story.html?p1=Article_Related_Box_Article_More accessed April 14, 2017.

¹⁶ Megan O'Matz, Limb-lengthening doctor faces state complaint, Sun Sentinel, March 13, 2016. Available at http://www.sun-sentinel.com/local/palm-beach/fl-doctor-dror-paley-20160318-story.html Accessed April 14, 2017.

¹⁷ American College of Surgeons, Statements on Principles, April 12 2016, *Available at https://www.facs.org/about-acs/statements/stonprin* accessed April 14, 2017.

¹⁸ Concurrent and Overlapping Surgeries: Additional Measures Warranted, A Senate Finance Committee Staff Report, December 6, 2016, available at https://www.finance.senate.gov/imo/media/doc/Concurrent%20Surgeries%20 Report%20Final.pdf Accessed April 14, 2017.

Interpretative Guidelines require that:

When a practitioner may perform certain surgical procedures under supervision, the specific tasks/procedures and the degree of supervision (to include whether or not the supervising practitioner is physically present in the same OR, inline of sight of the practitioner being supervised be delineated in that practitioner's surgical privileges and included on the surgical roster. ¹⁹ (Emphasis added.)

Thus, the organization should ensure that medical staff policy and privileges, as well as policies in the surgical suites, should address the issue of concurrent, simultaneous, or overlapping surgeries.

American College of Surgeons Statement on Principles

While the ACS statement should be taken in its entirety, section II.D addresses many of the concerns surrounding physician presence and the responsibility of the surgeon:

D. The Operation – Intraoperative Responsibility of the Primary Surgeon

General Statement

The primary attending surgeon is personally responsible for the patient's welfare throughout the operation. In general, the patient's primary attending surgeon should be **in the operating suite or should be immediately available for the entire surgical procedure.** There are instances consistent with good patient care that are valid exceptions. However, when the primary attending surgeon is not present or immediately available, another attending surgeon should be assigned to be "immediately available."

The *definitions at the end of this Statement* provide essential clarification for terms used herein.

Concurrent or Simultaneous Operations

Concurrent or simultaneous operations occur when the critical or key components of the procedures for which the primary attending surgeon is responsible are occurring all or in part at the same time. The critical or key components of an operation are determined by the primary attending surgeon. A primary attending surgeon's involvement in concurrent or simultaneous surgeries on two different patients in two different rooms is inappropriate.

Overlapping Operations

Overlap of two distinct operations by the primary attending surgeon occurs in two general circumstances.

The first and most common scenario is when the key or critical elements of the first operation have been completed, and there is no reasonable expectation that the primary attending surgeon will need to return to that operation. In this circumstance, a second operation is started in another operating room while a qualified practitioner performs

¹⁹ State Operations Manual Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf p.457.

noncritical components of the first operation – for example, wound closure – allowing the primary surgeon to initiate the second operation. In this situation, a qualified practitioner must be physically present in the operating room of the first operation.

The second and less common scenario is when the key or critical elements of the first operation have been completed and the primary attending surgeon is performing key or critical portions of a second operation in another room. In this scenario, the primary attending surgeon must assign immediate availability in the first operating room to another attending surgeon.

The patient needs to be informed in either of these circumstances. The performance of overlapping procedures should not negatively affect the seamless and timely flow of either procedure.

Multidisciplinary Operations

Contemporary surgical care often involves a multidisciplinary team of surgeons. During such operations, it is appropriate for surgeons to be present only during the part of the operation that requires their surgical expertise. However, an attending surgeon must be immediately available for the entire operation.

Delegation to Qualified Practitioners

The surgeon may delegate part of the operation to qualified practitioners including but not limited to residents, fellows, anesthesiologists, nurses, physician assistants, nurse practitioners, surgical assistants, or another attending under his or her personal direction. However, the primary attending surgeon's personal responsibility cannot be delegated. The surgeon must be an active participant throughout the key or critical components of the operation. The overriding goal is the assurance of patient safety.

Procedure-related Tasks

A primary attending surgeon may have to leave the operating room for a procedure-related task, such as review of pertinent pathology ("frozen section") and diagnostic imaging, discussion with the patient's family, and breaks during long procedures. The surgeon must be immediately available for recall during such absences.

Unanticipated Circumstances

Unanticipated circumstances may arise during procedures that require the surgeon to leave the operating room before completion of the critical portion of the operation. In this situation, a backup attending surgeon must be identified and available to come to the operating room promptly.

Circumstances in this category might include sudden illness or injury to the surgeon, a life-threatening emergency elsewhere in the operating suite or contiguous hospital building, or an emergency in the surgeon's family.

If more than one emergency occurs simultaneously, the attending surgeon may oversee more than one operation until additional attending surgeons are available.

Surgeon-Patient Communication (see Section II.A.)

The surgical team involved in an operation is dependent on the type of facility where

the operation is performed and on the complexity of the surgical procedure. At a freestanding outpatient surgery center, many procedures are performed solely by the primary attending surgeon with no assistant. In contrast, a complex procedure at an academic medical center may involve multiple qualified medical providers in addition to the primary attending surgeon. As part of the preoperative discussion, patients should be informed of the different types of qualified health care professionals who will participate in their operation (assistant attending surgeon, fellows, residents and interns, physician assistants, nurse practitioners, and so forth) and their respective role should be explained. If an urgent or emergent situation arises that requires the surgeon to leave the operating room unexpectedly, the patient should be informed subsequently.²⁰ (Emphasis added.)

The definitions furnished by the ACS are also useful to establish a common understanding and standardization of terms in policy:

Backup surgeon/surgical attending

The qualified surgical attending who has been designated to provide immediately available coverage for an operation, during a period when the primary surgeon might be unable to fill this role.

Concurrent or simultaneous operations

Surgical procedures when the critical or key components of the procedures for which the primary attending surgeon is responsible are occurring all or in part at the same time.

"Critical" or "key" portions of an operation

The "critical" or "key" portions of an operation are those stages when essential technical expertise and surgical judgment are necessary to achieve an optimal patient outcome. The critical or key portions of an operation are determined by the primary attending surgeon.

Immediately available

Reachable through a paging system or other electronic means, and able to return immediately to the operating room. This term should be defined more completely by the local institution.

Informed consent

Described in American College of Surgeons Statements on Principles II.A.

Multidisciplinary operations

An example of a multidisciplinary operation is a procedure in which a surgeon of one specialty provides the exposure required by a second surgeon who performs the main surgical intervention (such as a general or thoracic surgeon providing exposure for a neurosurgeon or orthopaedist to operate on the spine). Another example would be an operation that requires the involvement of two or more surgeons of different specialties (such as chest wall or head and neck resection followed by plastic surgical reconstruction, face or hand transplantation, and repair of complex craniofacial defects).

²⁰ American College of Surgeons, Statements on Principles, April 12 2016. Available at https://www.facs.org/about-acs/statements/stonprin accessed April 14, 2017.

"Overlapping or sequenced" operations for surgeons

The practice of the primary surgeon initiating and participating in another operation when he or she has completed the critical portions of the first procedure and is no longer an essential participant in the final phase of the first operation. These are by definition surgical procedures where key or critical portions of the procedure are occurring at different times.

Physically present

Located in the same room as the patient.

Primary attending surgeon

Considered the surgical attending of record or the principal surgeon involved in a specific operation. In addition to his or her technical and clinical responsibilities, the primary surgeon is responsible for the orchestration and progress of a procedure.

Qualified practitioner

Any licensed practitioner with sufficient training to conduct a delegated portion of a procedure without the need for more experienced supervision and who is approved by the hospital for these operative or patient care responsibilities.²¹ (Emphasis added.)

The "Critical or Key Components"

The lack of specificity regarding what constitutes the "critical or key component," as defined by the ACS, poses a challenge to policymakers who want to establish clear organizational guidelines for practice. Does each surgeon decide in the moment, on a case-per-case basis? Are there common portions of certain procedures for which all surgeons can agree require their physical presence? Does the decision vary based on which individuals on that particular day are scrubbed into a case? Is the critical component definition the same when a resident is the assistant as it is for a PA/NP?

Medicare Payment Policy: Teaching Physician

The *Medicare Claims Processing Manual* provides some insight as to what CMS views as a critical portion in the teaching physician payment rules:

§100.1.2 - Surgical Procedures

(Rev. 2303, Issued: 09-14-11, Effective: 06-01-11, Implementation: 07-26-11) In order to bill for surgical, high-risk, or other complex procedures, the teaching physician must be present during all critical and key portions of the procedure and be immediately available to furnish services during the entire procedure.

A. Surgery (Including Endoscopic Operations)

The teaching surgeon is responsible for the preoperative, operative, and postoperative care of the beneficiary. The teaching **physician's presence is not required during the opening and closing of the surgical field** unless these activities are considered to be critical or key portions of the procedure.²² (Emphasis

²¹ American College of Surgeons, *Statements on Principles*, April 12 2016, *Available at https://www.facs.org/about-acs/statements/stonprin* accessed April 14, 2017.

²² Medicare Claims Processing Manual Chapter 12 - Physicians/Nonphysician Practitioners, §100.1.2, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf Accessed April 14, 2017.

added.)

This section of the manual also addresses "overlapping surgeries":

2. Two Overlapping Surgeries

In order to bill Medicare for two overlapping surgeries, the teaching surgeon must be present during the critical or key portions of both operations. Therefore, the critical or key portions may not take place at the same time. When all of the key portions of the initial procedure have been completed, the teaching surgeon may begin to become involved in a second procedure. The teaching surgeon must personally document in the medical record that he/she was physically present during the critical or key portion(s) of both procedures. When a teaching physician is not present during non-critical or non-key portions of the procedure and is participating in another surgical procedure, he/she must arrange for another qualified surgeon to immediately assist the resident in the other case should the need arise. In the case of three concurrent surgical procedures, the role of the teaching surgeon (but not anesthesiologist) in each of the cases is classified as a supervisory service to the hospital rather than a physician service to an individual patient and is not payable under the physician fee schedule.²³

It is important to note that PAs and NPs have their own Medicare benefit categories, they are not residents, and the "teaching" payment rules do not apply to PAs and NPs. However, this section of the Medicare manual appears to be the only instance where Medicare addresses the "critical/key portion" issue, and serves as an illustration for consideration when framing policy and privileges.

Medicare Payment Policy-False Claims Liability

An additional consideration for the surgeon's presence during the "critical" portion of the surgery is the consequences of submitting a claim for the procedure to the Medicare program. The federal False Claims Act $(FCA)^{24}$ "imposes liability on any person who submits a claim to the federal government that he or she knows (or should know) is false. An example may be a physician who submits a bill to Medicare for medical services she knows she has not provided."²⁵ In the case of concurrent surgeries, if the surgeon were not present for a component of the surgery for which he submitted a claim, would he risk liability under the FCA?

Consider the scenario where the surgeon submits a claim for a lumbar decompression and fusion, multiple levels, with bone graft and instrumentation. The surgeon is present for the decompression and the first two levels of the fusion, with the PA on the other side of the table. The surgeon then leaves the PA to lay down the final bone graft and insertion of hardware on the final vertebral segment. Was the surgeon present for the bone graft and instrumentation at each level? Will the record reflect that he or she exited the operating room before the implants went in? Has the surgeon submitted a claim for services that he/she knows he has not provided?

²³ Id.

²⁴ 31 U.S. Code § 3729

²⁵ CMS Archive -False Claims Act, available at https://downloads.cms.gov/cmsgov/archived-downloads/smdl/downloads/smd032207att2.pdf Accessed April 14, 2017.

Enforcement Activity

The recent Department of Justice press release, False Claims Act Violation by UPMC Resolved for \$2.5 Million, sheds some light on what appears to be a similar scenario to that posed above:

The settled claims contended that UPMC violated the False Claims Act by submitting false claims for payment to the Medicare program. Specifically, the Complaint alleged that certain neurosurgeons employed by UPMC submitted claims for assisting with or supervising surgical procedures performed by other surgeons, residents, fellows, or physician assistants, when those neurosurgeons did not participate in the relevant surgeries to the degree required. The settlement also resolves allegations that a particular neurosurgeon, when performing multi-level spinal surgeries, submitted claims to the Medicare program for levels of spinal decompression not actually performed. (Emphasis added.)

Conclusion

- The facility must have policy. In the absence of policy and specificity in privileging, the surgeon likely needs to be present in the operating room for the duration of the procedure. Without policy and appropriate privileging, there is little recourse should things go awry.
- The physician ultimately determines the "critical portion" of the procedure: billing rules and ramifications should also be taken into consideration when making this determination.
- CMS does not consider closure "critical" unless the surgeon has determined it to be.
- State laws for PA/NP supervision must be met.
- Malpractice carriers should be consulted to weigh in on coverage policy for overlapping surgeries.

²⁶ U.S. Dep't of Justice, U.S. Attorney's Office, Western District of Pennsylvania, Press Release, *False Claims Act Violation by UPMC Resolved for \$2.5 Million*, July 27, 2016. *Available at https://www.justice.gov/usao-wdpa/pr/false-claims-act-violation-upmc-resolved-25-million* Accessed April 14, 2017.

Competency Assessment









Competencies for the Physician Assistant Profession

(Originally adopted 2005; revised 2012)

Preamble

Between 2003 and 2004, the National Commission on Certification of Physician Assistants (NCCPA) led an effort with three other national PA organizations (Accreditation Review Commission on Education for the Physician Assistant [ARC-PA], AAPA, and the Physician Assistant Education Association [PAEA]) to define PA competencies in response to similar efforts conducted within other healthcare professions and the growing demand for accountability and assessment in clinical practice. The resultant document, *Competencies for the Physician Assistant Profession*, provided a foundation from which physician assistant organizations and individual physician assistants could chart a course for advancing the competencies of the PA profession.

This document was updated in 2012 and then approved in its current form by the same four organizations.

Introduction

This document serves as a map for the individual PA, the physician-PA team, and organizations committed to promoting the development and maintenance of professional competencies among physician assistants. While some competencies will be acquired during formal PA education, others will be developed and mastered as physician assistants progress through their careers. The PA profession defines the specific knowledge, skills, attitudes, and educational experiences requisite for physician assistants to acquire and demonstrate these competencies.

The clinical role of PAs includes primary and specialty care in medical and surgical practice settings. Professional competencies for physician assistants include the effective and appropriate application of medical knowledge, interpersonal and communication skills, patient care, professionalism, practice-based learning and improvement, and systems-based practice.

Patient-centered, physician assistant practice reflects a number of overarching themes. These include an unwavering commitment to patient safety, cultural competence, quality healthcare, lifelong learning, and professional growth. Furthermore, the profession's dedication to the physician-physician assistant team benefits patients and the larger community.



Physician Assistant Competencies

Medical Knowledge

Medical knowledge includes the synthesis of pathophysiology, patient presentation, differential diagnosis, patient management, surgical principles, health promotion, and disease prevention. Physician assistants must demonstrate core knowledge about established and evolving biomedical and clinical sciences and the application of this knowledge to patient care in their area of practice. In addition, physician assistants are expected to demonstrate an investigative and analytic thinking approach to clinical situations. Physician assistants are expected to understand, evaluate, and apply the following to clinical scenarios:

- Evidence-based medicine
- Scientific principles related to patient care
- Etiologies, risk factors, underlying pathologic process, and epidemiology for medical conditions
- Signs and symptoms of medical and surgical conditions
- Appropriate diagnostic studies
- Management of general medical and surgical conditions to include pharmacologic and other treatment modalities
- Interventions for prevention of disease and health promotion/maintenance
- Screening methods to detect conditions in an asymptomatic individual
- History and physical findings and diagnostic studies to formulate differential diagnoses

Interpersonal & Communications Skills

Interpersonal and communication skills encompass the verbal, nonverbal, written, and electronic exchange of information. Physician assistants must demonstrate interpersonal and communication skills that result in effective information exchange with patients, patients' families, physicians, professional associates, and other individuals within the healthcare system. Physician assistants are expected to:

- Create and sustain a therapeutic and ethically sound relationship with patients.
- Use effective communication skills to elicit and provide information.
- Adapt communication style and messages to the context of the interaction.
- Work effectively with physicians and other healthcare professionals as a member or leader of a healthcare team or other professional group.
- Demonstrate emotional resilience and stability, adaptability, flexibility, and tolerance of ambiguity and anxiety.
- Accurately and adequately document information regarding care for medical, legal, quality, and financial purposes.

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Patient Care

Patient care includes patient- and setting-specific assessment, evaluation, and management. Physician assistants must demonstrate care that is effective, safe, high quality, and equitable. Physician assistants are expected to:

- Work effectively with physicians and other healthcare professionals to provide patientcentered care.
- Demonstrate compassionate and respectful behaviors when interacting with patients and their families.
- Obtain essential and accurate information about their patients.
- Make decisions about diagnostic and therapeutic interventions based on patient information and preferences, current scientific evidence, and informed clinical judgment.
- Develop and implement patient-management plans.
- Counsel and educate patients and their families.
- Perform medical and surgical procedures essential to their area of practice.
 provide healthcare services and education aimed at disease prevention and health maintenance.
- Use information technology to support patient care decisions and patient education.

Professionalism

Professionalism is the expression of positive values and ideals as care is delivered. Foremost, it involves prioritizing the interests of those being served above one's own. Physician assistants must acknowledge their professional and personal limitations. Professionalism also requires that PAs practice without impairment from substance abuse, cognitive deficiency or mental illness. Physician assistants must demonstrate a high level of responsibility, ethical practice, sensitivity to a diverse patient population, and adherence to legal and regulatory requirements. Physician assistants are expected to demonstrate:

- Understanding of legal and regulatory requirements, as well as the appropriate role of the physician assistant.
- Professional relationships with physician supervisors and other healthcare providers.
- Respect, compassion, and integrity.
- Accountability to patients, society, and the profession.
- Commitment to excellence and ongoing professional development.
- Commitment to ethical principles pertaining to provision or withholding of clinical care, confidentiality of patient information, informed consent, and business practices.
- Sensitivity and responsiveness to patients' culture, age, gender, and abilities.
- Self-reflection, critical curiosity, and initiative.
- Healthy behaviors and life balance.
- Commitment to the education of students and other healthcare professionals.

Practice-based Learning & Improvement

Practice-based learning and improvement includes the processes through which physician assistants engage in critical analysis of their own practice experience, the medical literature, and other information resources for the purposes of self- and practice-improvement. Physician assistants must be able to assess, evaluate, and improve their patient care practices. Physician assistants are expected to:

- Analyze practice experience and perform practice-based improvement activities using a systematic methodology in concert with other members of the healthcare delivery team.
- Locate, appraise, and integrate evidence from scientific studies related to their patients' health.
- Apply knowledge of study designs and statistical methods to the appraisal of clinical literature and other information on diagnostic and therapeutic effectiveness.
- Utilize information technology to manage information, access medical information, and support their own education.
- Recognize and appropriately address personal biases, gaps in medical knowledge, and physical limitations in themselves and others.

Systems-based Practice

Systems-based practice encompasses the societal, organizational, and economic environments in which healthcare is delivered. Physician assistants must demonstrate an awareness of and responsiveness to the larger system of healthcare to provide patient care that balances quality and cost, while maintaining the primacy of the individual patient. PAs should work to improve the healthcare system of which their practices are a part. Physician assistants are expected to:

- Effectively interact with different types of medical practice and delivery systems.
- Understand the funding sources and payment systems that provide coverage for patient care and use the systems effectively.
- Practice cost-effective healthcare and resource allocation that does not compromise quality of care.
- Advocate for quality patient care and assist patients in dealing with system complexities.
- Partner with supervising physicians, healthcare managers, and other healthcare
 providers to assess, coordinate, and improve the delivery and effectiveness of healthcare
 and patient outcomes.
- Accept responsibility for promoting a safe environment for patient care and recognizing and correcting systems-based factors that negatively impact patient care.
- Apply medical information and clinical data systems to provide effective, efficient patient care
- Recognize and appropriately address system biases that contribute to healthcare disparities.
- Apply the concepts of population health to patient care.

PAs: Assessing Clinical Competence

Guide for regulators, hospitals, employers and third-party payers

Physician assistants (PAs) are versatile members of the medical team, with broad, yet rigorous medical training. PAs practice in every medical and surgical specialty and every practice setting, providing a broad range of services that would otherwise be provided by physicians. They are graduates of accredited PA programs, licensed, and nationally certified.

PA education is conducted at the master's level and modeled on physician education. Applicants must complete at least two years of college courses in basic and behavioral sciences as prerequisites.

PA education programs average 26 months in length. The first year of PA school provides a broad grounding in medical principles and instruction in the classroom and lab. Year one consists of basic medical science courses, including anatomy, physiology, biochemistry, pharmacology, physical diagnosis, pathophysiology, microbiology, clinical laboratory sciences, behavioral sciences, and medical ethics. In the second year, PA students receive hands-on clinical training through rotations that include family medicine, internal medicine, obstetrics and gynecology, pediatrics, general surgery, emergency medicine, and psychiatry. PA students complete on average more than 2,000 hours of supervised clinical practice prior to graduation. There are more than 187 PA programs accredited by the Accreditation Review Commission on Education for the Physician Assistant.

Upon graduation from a physician assistant program, PAs must pass the Physician Assistant National Certifying Examination (PANCE), the initial certifying exam administered by National Commission on Certification of Physician Assistants. Starting in 2014, NCCPA's Certification Maintenance Requirements changed, with enhanced CME requirements and re-examination extended to a 10-year cycle, to mirror the Maintenance of Certification® requirements for physicians. PAs will transition from a six-year cycle to the 10-year cycle at their next recertification due date. While all states require initial certification for initial licensure, not all states require maintenance of current certification for licensure renewal.

Unlike physicians, PAs do not have specialty board exams. They specialize by virtue of the physicians with whom they work.

Credentialing PAs

Organizations credential healthcare professionals to ensure that patients receive high-quality

^{1.} Physician Assistant Education Association. (2008–2009). Twenty-fourth annual report on physician assistant educational programs in the United States. Alexandria, VA.

^{2.} Association of Physician Assistant Programs. (1994–1995). Physician Assistant Education Programs in the United States. Washington, DC.

^{3.} Accreditation Review Commission on Education for the Physician Assistant, http://www.arc-pa.org/acc_programs/ Retrieved September 25, 2014.

^{4.} NCCPA: NEW CERTIFICATION PROCESS OVERVIEW http://www.nccpa.net/CertMain Retrieved September 25, 2014

medical care. Hospitals, healthcare organizations, practices, and third-party payers use varied systems for doing this. Many organizations adapt physician forms and criteria to create a parallel process for PAs.

For PAs, primary sources include:

- State licensing board to confirm that the applicant is properly licensed.
- Accredited PA program for graduation information.
- National Commission on Certification of Physician Assistants (NCCPA) to confirm initial and ongoing national certification. Go to www.nccpa.net.
- National Practitioner Data Bank (NPDB) for malpractice and adverse actions history.

The American Medical Association's (AMA) Physician Profile Service offers PA credentials verification. For a nominal fee, credentialing professionals can confirm a PA's education, program attendance and graduation dates, national certification number and status, current and historical state licensure information, and AAPA membership status. The Joint Commission has deemed that the information provided by the AMA service is equivalent to primary source information

Similarly, the Federation of State Medical Boards offers its Federation Credential Verification Service to PAs.

PA Primary Source Verification

- State license
- · Graduation from accredited program
- National certification
- NPDB/HIPDB check

Privileging PAs in Hospitals

Because of the breadth and rigor of PA education programs, students graduate with skills that are fundamental and essential to every specialty – a fund of medical knowledge, interpersonal and communication skills, patient care, including the ability to provide age-appropriate patient assessment, evaluation and management, professionalism, practice-based learning and improvement, and systems-based practice. PAs providing care in the hospital must be privileged through the medical staff process, whether they are employed by the hospital or by an outside practice.

Core Privileges

Some organizations identify core privileges that may be granted to any PA who meets the organization's criteria. Core privileges may vary depending upon the clinical department. They include, but are not limited to such things as performing histories and physicals,

^{5.} Competencies for the Physician Assistant Profession (Originally adopted 2005; revised 2012) http://www.nccpa.net/App/PDFs/Definition%20of%20PA%20Competencies%203.5%20for%20Publication.pdf

^{6.} Guidelines for Updating Medical Staff Bylaws: Credentialing and Privileging Physician Assistants (AAPA Policy 2012) https://www.aapa.org/wp-content/uploads/2017/01/HP_PAs_HospitalPractice.pdf Retrieved September 25, 2014

developing and implementing treatment plans, performing rounds, recording operative and procedure notes, recording progress notes, ordering and interpreting diagnostic laboratory tests and diagnostic imaging studies, ordering medications and writing prescriptions, managing fractures, suturing lacerations, performing corneal fluorescein exams and foreign body removal, providing anterior nasal packing for epistaxis, administering trigger point injections, incising and draining abscesses, and performing discharge summaries. This listing of PA core privileges is not meant to be exhaustive. There could be other core privileges, depending on the institution and department.

Specialty Privileges

PA medical education is broad. PA students master clinical fundamentals that prepare them to practice with physicians in virtually every area of medicine and surgery. However, unlike physicians, PAs do not have specialty board exams. They specialize by virtue of the physicians with whom they work.

When PAs are evaluated for specialty privileges, hospitals can verify their competence through a number of means, including:

- Attestation to the PA's competence by physicians and PA peers.
- Hospital systems that track clinical activity.
- Data collected for initiatives such as the Surgical Care Improvement Project (SCIP) or the Physician Quality Reporting System (PQRS).
- Requiring a certain percentage of continuing medical education credits specific to the specialty.
- Requiring maintenance of pertinent certifications such as Basic Life Support, Advanced
 Cardiac Life Support, Advanced Trauma Life Support, Pediatric Advanced Life Support, etc.
- Certificates of completion from relevant clinical courses.
- Use of simulation labs to assess cognitive and procedural competence.
- Professional portfolio in which the PA documents procedures and patient care provided.

When a PA is a recent graduate or is changing specialties, it may be necessary to facilitate proctoring by a physician or senior PA until the PA requesting privileges can demonstrate competence.

FPPE and OPPE

Joint Commission-accredited hospitals are required to include PAs in their focused professional practice evaluations (FPPE) and ongoing professional practice evaluations (OPPE), which are intended to help ensure the competence of providers. Data for the ongoing evaluation is acquired from periodic chart review, direct observation, procedures logs, peer review, monitoring of diagnostic and treatment techniques, and input from other individuals involved in the care of the same patients, including clinicians and administrators.

Regulatory Agencies and Insurers

State regulatory agencies and third-party insurance companies typically leave the determination of an individual PA's specialty and scope of practice up to the physicians with whom the PA works. This ranges from solo physicians through large multi-specialty practices, to major healthcare systems. A PA working in a particular specialty has oversight and guidance by a physician in that specialty. Because the physicians and PAs work closely together, they are the individuals most able to determine the appropriate specifics of a PA's day-to-day practice, based on the PA's training and experience, patient needs, and the needs of the particular practice.

Sample Competency Assessment Tool

Introduction

This Sample Competency Tool serves as a corollary to the foundational document, *Competencies for the PA Profession*. Of note, there are significant similarities to the competencies required of physicians, as the education training of a PA mirrors that of the physician. Therefore, the competency assessment (FPPE/OPPE in Joint Commission-accredited facilities) policy for PAs will often mirror that of the physicians in the same specialty.

Professional competencies for PAs include:

- The effective and appropriate application of medical knowledge.
- Interpersonal and communication skills.
- Patient care, professionalism.
- Practice-based learning and improvement.
- Systems-based practice.

The first two pages of the attached Sample Tool can be considered "core competencies" for the profession, and will apply to all PAs regardless of specialty. The third page is drawn from the specialty/department specific privileges granted; these vary widely by specialty and setting. The competencies selected are determined by the department/department chair and approved by the medical staff.

Additional Resources

Physician Assistants: Assessing Clinical Competence (PDF)

This is a useful guide for regulators, hospitals, employers, and third-party payers.

FPPE and OPPE Are More than Just Acronyms (PDF)

This article, published in AAPA's magazine, PA Professional, speaks to the Joint Commission requirements (and challenges) for Focused Professional Performance Evaluation and Ongoing Professional Performance Evaluation.

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Physician Assistant Competency Measures

COMPETENCY MEASURE Note: A score of 1 or 2 requires comment in the space provided.	UNACCEPTABLE Clearly inadequate; requires remediation	POOR Many deficiencies	SATISFACTORY Adequate	VERY GOOD Exceeds in many areas- top 20%	EXCELLENT Superior in every way- top 10%
Patient Care (and Procedures) History taking: accurate and complete Physical exam: required components present Complete assessment and plans Provides quality patient education Competently performs medical and surgical procedures delineated by medical staff privileges-overall evaluation (See page 3 for department specific privilege, focused evaluations.)	1 1 1 1 1 1 1	2 2 2 2 2	ოოოო ო ო	4 4 4 4 4	ט טטטטט
Appropriate selection of diagnostic tests Appropriate interpretation/analysis of test results Appropriate integration of history and physical findings and diagnostic studies to formulate a differential diagnosis Overall integration of clinical information into treatment planning Pharmacological knowledge/appropriate ordering of therapeutics	1 1 1 1	2 2 2 2	ммм м	4 4 4 4 4	വ വ വവ
Practice-Based Learning and Improvement Applies evidence-based medicine to clinical decisions Awareness of quality improvement measures and application to clinical practice Facilitates the learning of students and other health care professionals	1 1 1	2 2 2	m m m	4 4 4	م م n

AAPA

Date of Evaluation:

PA Name: _



Physician Assistant Competency Measures

COMPETENCY MEASURE Note: A score of 1 or 2 requires comment in the space provided.	UNACCEPTABLE Clearly inadequate; requires remediation	POOR Many deficiencies	SATISFACTORY Adequate	VERY GOOD Exceeds in many areas- top 20%	EXCELLENT Superior in every way- top 10%
Professionalism Displays sensitivity and responsiveness to patients' culture, age, gender, and disabilities Understanding of the legal and regulatory requirements governing PA practice and the role	1 1	2 2	m m	4 4	വ വ
of the PA Commitment to personal excellence and ongoing professional development	1	2	က	4	Ŋ
Interpersonal & Communication Skills					
Communications and behaviors with patients are effective and appropriate	П	2	က	4	വ
Communications and behaviors with physician supervisors are effective and appropriate	П	2	က	4	വ
Demonstrates emotional resilience and stability, adaptability, flexibility, and tolerance of ambiguity and anxiety	1	2	ന	4	വ
Uses effective listening, nonverbal, explanatory, interviewing, and writing skills to elicit and provide information	1	2	က	4	വ
Systems Based Practice					
Uses information technology resources to support patient care decisions and patient education	1	2	М	4	വ
Practices cost-effective health care and resources allocation that does not compromise quality of care	1	2	м	4	ഗ
Applies medical information and clinical data systems to provide more effective, efficient patient care	1	2	м	4	ഗ
					ঠ

AAPA

PA Name: _



Physician Assistant Competency Measures

COMPETENCY MEASURE-ORTHOPAEDICS Note: A score of 1 or 2 requires comment in the space provided.	UNACCEPTABLE Clearly inadequate; requires remediation	POOR Many deficiencies	SATISFACTORY Adequate	VERY GOOD Exceeds in many areas- top 20%	EXCELLENT Superior in every way- top 10%
X-ray Interpretation Demonstrates accurate interpretation of findings Provides complete documentation	1	2 2	с с	4 4	വവ
Fracture/Dislocation Reduction Demonstrates appropriate technique Achieves acceptable alignment Provides appropriate post-reduction management/immobilization	1 1 1	2 2 2	m m m	4 4 4	ט ט ט
Cast/Splint Application Demonstrates appropriate technique Applies appropriate splint type and selects appropriate materials	1 1	2 2	m m	4 4	വ
Assistant at Surgery Maintains sterile technique Demonstrates appropriate patient positioning/ draping Provides effective retraction/exposure Demonstrates acceptable wound closure techniques, including approximation of layers, selection of closure material, and dressing application	1 1 1 1	0 0 0 0	m m m m	4 4 4 4	വ വ വ
Medical Management Antibiotics ordered appropriately (1 hour prior to surgery, stopped in 24 hours post-op, appropriate drug selected) DVT prophylaxis ordered appropriately Pain management appropriate	1 1 1	N N N	m m m	4 4 4	N N N

AAPA

Date of Evaluation:

PA Name:



Evaluator Level of Interaction:

Minimum-occasional encounters Moderate-weekly encounters Extensive-daily encounters

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Physician (MD/DO) Peer (PA)





(60)

FPPE and OPPE Are More than Just Acronyms But What Does It Mean to ME?

PA PROFESSIONAL, DECEMBER 2010



In the vocabulary of hospital medicine, acronyms, abbreviations and initialisms are ubiquitous and well understood by PAs. When faced with the notation "75 y.o. w.m. w/hx/o IDDM, CHF, HTN, CAD and RA presents with CC/o CP and SOB," it's quite clear that a 75-year-old white male with a history of insulin-dependent diabetes mellitus, congestive heart failure, coronary artery disease and rheumatoid arthritis presents with chief complaint of chest pain and shortness of breath.

Yet, many PAs are stumped by the acronyms FPPE and OPPE. Focused Professional Performance Evaluation, or FPPE, and Ongoing Professional Practice Evaluation, or OPPE, are Joint Commission standards from the Medical Staff chapter of the Comprehensive Accreditation Manual for Hospitals and Comprehensive Accreditation Manual for Critical Access Hospitals.

FPPE and OPPE affect PAs and other practitioners who are credentialed and privileged through the medical staff process. A hospital's failure to complete the FPPE/OPPE process might result in a Joint Commission citation. The Joint Commission has required hospitals to

do FPPEs and OPPEs since 2008, but hospital administrators and medical staff continue to struggle with these requirements.

Credentialing refers to the process applied by hospitals to verify a practitioner's current licensure, relevant education and training, and competence to perform the privileges requested. Based on objective data, recommendations are made for granting or denying initial privileges, renewal of privileges or granting/denying new privileges.

Once credentialing has been done, the privileging process can begin. There are three prongs to the privileging process: Requested privileges are approved based on criteria established by the medical staff; The medical staff 's FPPE process ensures that the practitioner meets competence and organizational expectations for initial privileges; and the practitioner must meet ongoing performance expectations.

FPPE and OPPE are each meant to establish the competence of the practitioner to perform the privileges granted in order to ensure the provision of safe and quality patient care.

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So let's commence with AAPA's FPPE/OPPE rundown:

FPPE is defined by the Joint Commission as: "the time-limited evaluation of practitioner competence in performing a specific privilege. This process is implemented for all initially requested privileges and whenever a question arises regarding a practitioner's ability to provide safe, high-quality patient care."

FPPE criteria are defined by the medical staff to monitor the performance of the practitioner. The time limit is also determined by the medical staff. Once the FPPE period has been completed, OPPE begins.

OPPE is a key component of determining practitioner competence for maintenance of clinical privileges. The ongoing assessment allows for identification of possible practice trends affecting patient safety. OPPE can also uncover opportunities for performance improvement activities. The Joint Commission defines ongoing professional practice evaluation as "a document summary of ongoing data collected for the purpose of assessing a practitioner's clinical competence and professional behavior. The information gathered during this process is factored into decisions to maintain, revise, or revoke existing privilege(s) prior to or at the end of the two-year license and privilege renewal cycle."

pointment process would not meet the standard.

A PA's clinical privileges are determined and delegated by supervising physicians and are aligned with the physicians' scope of practice. As such, OPPE criteria for PAs should be similar to those for physicians. AAPA's policy "Competencies for the PA Profession" references the ABMS/ ACGME six core competencies for physicians as a standard, and mirrors the

concepts defined by the Joint Commission in the introduction to the OPPE standard:

Data must be ongoing, so waiting for an annual review or the two-year recredentialing/reap-

- 1. Medical knowledge
- 2. Practice-based learning and improvement
- 3. Interpersonal and communications skills
- 4. Professionalism
- 5. Systems-based practice
- 6. Patient care

Of note, ACGME and ABMS are updating the six core competencies for physician performance measurement, which they developed in 1999. The competency previously known as "patient care" will be referred to as "patient care and procedural skills." "Procedural skills" is categorized as a sub-set of the patient care core competency for which practitioners demonstrate proficiency.

Defining criteria for performance measurement is one of the biggest challenges for organizations. Performance data are not readily extractable from many hospital computer systems, making data collection a manual process, which is labor intensive and time-consuming. Thus, organizations are looking to create an effective process, while facing enormous challenges within their own systems.

The Joint Commission does not specify which criteria must be monitored. In fact, it states that the type of data to be collected is determined by the individual department and approved by the medical staff. Since OPPE data are used to determine maintenance of privileges, criteria should correlate with core competencies as well as the clinical privileges granted to the practitioner. Data used for the ongoing evaluation may be acquired via periodic chart review, direct observation, procedure logs, peer review, monitoring of diagnostic and treatment techniques, and input from other individuals involved in the care of the patient, such as other practitioners or administrative personnel.

Quality measures from initiatives such as the Surgical Care Improvement Project, SCIP, or the Physician Quality Reporting Initiative, PQRI, are most likely already being collected by the hospital. The Health Information Management Department (aka "Medical Records") monitors chart completion delinquencies. "Do Not Use" abbreviations are also monitored. These data, already being collected, can also be applied to the OPPE process for each practitioner—no need to invent new measures. Hospitals must find a way to share the practitioner-specific data with the appropriate department(s) responsible for OPPE.

The ultimate goal of FPPE/OPPE is to ensure quality care and patient safety by monitoring the competence, activities and behavior of practitioners privileged to provide patient care. Joint Commission surveyors will be looking for documentation of the hospital's FPPE/OPPE processes and how they are applied to the credentialing and privileging process for its practitioners, including PAs.

For more detailed information on FPPE, go the Joint Commission website, http://bit.ly/9f6Hcl OPPE detailed information is located at http://bit.ly/aVq9qh

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AAPA has created a sample, PA-specific, FPPE/ OPPE form. For more information on the form, contact Tricia Marriott at tmarriott@aapa.org.

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Business Case: PA/NP Contribution to the Global Surgical Package

Introduction

Academic medical centers (AMC), as well as community hospitals that serve as resident training sites, have had provider workforce challenges since the Accreditation Council for Graduate Medical Education (ACGME) first imposed resident physician work-hour restrictions in 2003,^{1,2,3} with further restrictions imposed in 2011.⁴ To mitigate what essentially amounted to a reduction to their medical provider workforce as a result of the decreased availability of resident physicians, many of these hospitals⁵ have hired PAs and NPs to provide medical care on the inpatient wards, in the outpatient clinics, in the operating room, the critical care units, and the emergency departments.^{6,7}

As the numbers of PAs/NPs continue to grow, and with no graduate medical education (GME) funding for them, surgical service line administrators find themselves challenged to justify the expense for the number of PA/NP full-time employees (FTEs). Due to the attribution of the global surgical package to the surgeon who performed the procedure (the work components as well as the reimbursement), the inability to quantify the revenue generated or overall value and contribution of the PA/NP defies cost-accounting principles and requires a conceptual approach.

¹ In response to the 1992 Libby Zion case, resident duty-hours came under great scrutiny. See Zion v. New York Hosp., 183 AD 2d 386 - NY: Appellate Div., 1st Dept. 1992.

² Norton Spritz, Oversight of Physicians' Conduct by State Licensing Agencies: Lessons from New York's Libby Zion Case, 115 ANNALS INTERNAL MED. 219, 219 (1991) "The unexplained and highly publicized death of an 18-year-old woman in a New York Hospital in 1984 became the focus for debate throughout the country concerning working conditions and supervision of house officers. It also led to charges by the State of New York of gross negligence against her resident physicians."

³ Peter D. Fabricant, et al., A Narrative Review of Surgical Resident Duty Hour Limits: Where Do We Go From Here?, 5 J. GRADUATE MED EDUC. 19-24, at 19 (Mar 2013), available at http://www.ncbi.nlm.nih.gov/pmc/articles/ PMC3613312/pdf/i1949-8357-5-1-19.pdf "Resident duty hour limits have been a point of debate among educators, administrators, and policymakers alike since the Libby Zion case in 1984."

⁴ Accreditation Council for Graduate Education, See generally Resident Duty Hours in the Learning and Working Environment: Comparison of 2003 and 2011 Standards, http://www.acgme.org/acgmeweb/Portals/0/PDFs/dh-ComparisonTable2003v2011.pdf

⁵ Marc Moote, et al., *Physician Assistant and Nurse Practitioner Utilization in Academic Medical Centers*, 26 Am. J. Med. QUALITY 452-460, (Nov. /Dec. 2011), *available at http://ajm.sagepub.com/content/26/6/452.* short?rss=1&ssource=mfr ("The primary reason cited by most AMCs for employing PAs and NPs was Accreditation Council for Graduate Medical Education resident duty hour restrictions...").

⁶ Supra note 3 Fabricant, at 23. "...further redistribution of ancillary staff and physician extenders (e.g., physician assistants, nurse practitioners) would allow for most of a resident's time to be spent on education and clinical care, rather than nonessential tasks."

⁷ Sharat K. et al., Measuring the attitudes and impact of the eighty-hour workweek rules on orthopaedic surgery residents. 89 J Bone Joint Surgery Am. 679, 679 (Mar 2007). "Eighty-two percent of the respondents indicated that their residency programs have been forced to make changes to their call schedules or to hire... staff to address the rules. The use of physician assistants, night-float systems, and so-called home-call assignments were the most common strategies used to achieve compliance."

Global Surgical Package Defined

CMS guidance provides the following definition for the global surgical package:

The global surgical package, also called global surgery, includes all necessary services normally furnished by a surgeon before, during, and after a procedure. Medicare payment for the surgical procedure includes the preoperative, intraoperative, and postoperative services routinely performed by the surgeon or by members of the same group with the same specialty. Physicians in the same group practice who are in the same specialty must bill and be paid as though they were a single physician.^{8,9}

Each procedure code has an assigned time frame, known as the global period, of 0, 10, or 90 days. This information is published for each CPT® code in the Medicare Physician Fee Schedule Look-up Tool,¹⁰ which also contains payment information, relative value units (RVUs), and the distribution of value for the preoperative, intraoperative and postoperative services provided.

As an example, the posted fee schedule value for the CPT® code 27130, "total hip arthroplasty," indicates a 90-day global period, with 10% of the value assigned to the preoperative work, 69% to the intraoperative work, and 21% assigned to the postoperative work provided over 90 days. The graphic below illustrates how this is displayed in the fee schedule:



⁸ Department of Health and Human Services, Centers for Medicare & Medicaid Services, Medicare Learning Network ®, *Global Surgery Fact Sheet*, ICN 907166, March 2015. *Available at:* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/GloballSurgery-ICN907166.pdf accessed April 17, 2017.

⁹ See also Department of Health and Human Services, Centers for Medicare & Medicaid Services, Medicare Claims Processing Manual, Chapter 12, §§ 40 and 40.1. Available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf accessed April 17, 2017.

¹⁰ CMS.gov, Centers for Medicare and Medicaid Services, *Medicare Physician Fee Schedule*, https://www.cms.gov/apps/physician-fee-schedule/overview.aspx.

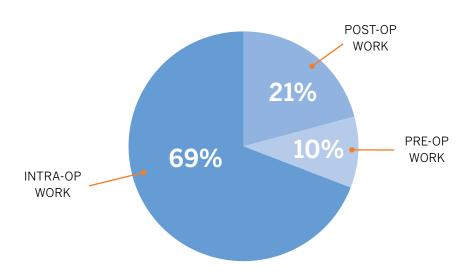
¹¹ Id.

¹² CMS.gov, Centers for Medicare and Medicaid Services, *Medicare Physician Fee Schedule*, https://www.cms.gov/apps/physician-fee-schedule/overview.aspx Screen shot compilation, accessed April 17, 2017.

Calculating PA/NP Contribution

Another way to view the global surgical package is to think of it in terms of a pie chart. The intraoperative work is solely attributed to the surgeon at 69%; the remaining 31% of the "global work" is often provided by other members of the surgical team, with varying levels of effort from the primary surgeon.

GLOBAL SURGICAL PACKAGE



Translated into revenue, the payment for our total hip arthroplasty would be sliced into the following:

Example:

CPT® 27130 total hip arthroplasty (THR) payable at \$1,401.13

Preop work: (10%): \$ 140.10
Postop work: (21%): \$ 294.21

Total: \$434.31 (surgeon plus PA/NP)

Intraop work (69%): \$ 966.69 (surgeon)

Work outside the OR comprises 31% of the global payment. If the PA/NP is providing any portion of the preoperative H&P, postoperative rounds, and postoperative office visits, then a **percentage** of the global payment could, theoretically, be applied to the PA/NP.

¹³ *Id.* National payment amount: final figure impacted by geographic index.

If the PA/NP provides **80**% of the preoperative and postoperative work, then **\$347.45** (**80**% of **\$434.31**) *could* be "credited or allocated" to PA/NP. **An additional separate payment of \$190.54** can be officially credited to the PA/NP for the first assist service (13.6% of surgeon's fee of \$1401).

Global "value" might be calculated to be:

First assist payment of \$190.54

Plus

Preop/postop share of global payment \$347.45

Total = \$537.99 per THA

If the practice performed 300 total hip arthroplasties, **revenue** attributed to the PA/NP might be

 $300 \times $537.99 = 161.397

This logic can be applied to most 90-day surgical procedure codes. The level of effort/percent contribution of the PA/NP will vary for each practice, as PA/NP utilization patterns vary widely.

The level of effort of the surgeon may also vary within the same practice based on the type of procedure provided: elective surgery often has a more predictable and standard postoperative course than emergency or unexpected surgical procedures. Nevertheless, the concept of the PA/NP contribution to the episode of care can be calculated accordingly.

Opportunity Loss/Cost

While not separately billed or payable, postoperative visits can be tracked in practice management software via CPT® 99024: "Postoperative follow-up visit included in global service," and by creating a "dummy code" for the preoperative history and physical (H+P), if those services are being provided by the PA/NP as a separate encounter from the "decision for surgery" visit. The global visits performed by the PA/NP would otherwise have to be performed by the physician, tying up otherwise revenue-generating physician slots. For example, if the PA/NP provided 300 postoperative global visits, 300 appointments were then made available for the physician to see revenue-generating visits. Utilizing the PA/NP to provide these visits can mitigate the surgeon's opportunity loss of revenue generation associated with the 90-day global work, creating opportunities for the surgeon to see new patients or perform more surgery.

¹⁴ American Medical Association, CPT® 2017 Professional Edition.

Contribution to Quality, Efficiency, and Performance

The PA/NP contribution to decreased length of stay, overall quality and safety benchmarks, and increased efficiencies are only recently emerging through published studies.^{15,16,17,18,19}

More research is needed to capture the intrinsic contribution that can be made by effective deployment of the PA and NP workforce in the era of bundled payments and potential future adoption of widespread non-fee-for-service payment methods.

¹⁵ Miranda Laurant, Mirjam Harmsen, Hub Wollersheim, Richard Grol, Marjan Faber & Bonnie Sibbald, Cost-Effectiveness of Health Care Services The Impact of Nonphysician Clinicians: Do They Improve the Quality and Cost-Effectiveness of Health Care Services? 66 Med. Care Research & Rev. 36S (2009). "The evidence suggests that nonphysician clinicians working as substitutes or supplements for physicians in defined areas of care can maintain and often improve the quality of care and outcomes for patients."

¹⁶ John P. Nabagiez, Masood A. Shariff, Muhammad A. Khan, William J. Molloy & Joseph T. McGinn, Jr, *Physician assistant home visit program to reduce hospital readmissions*, 145 J. THORACIC & CARDIOVASCULAR SURGERY 225-33 (2013). (Conclusions: The 30-day readmission rate was reduced by 25% in patients receiving PA Home Care visits.).

¹⁷ Marc Moote, et al., *PA-driven VTE risk assessment improves compliance with recommended prophylaxis*, 23 J. of Am. Acad. of Physician Assistants, 27-35(2010), *available at* http://www.ncbi.nlm.nih.gov/pubmed/20653258 ("Conclusion: A physician assistant-driven VTE risk assessment process resulted in a dramatic increase in the number of patients within the health system who were prescribed appropriate orders for VTE prophylaxis according to published guidelines and according to individual patient risk.")

¹⁸ Peter L. Althausen, Steven Shannon, Brianne Owens, Daniel Coll, Michael Cvitash, Minggen Lu, Timothy J. O'Mara, and Timothy J. Bray, *Impact of Hospital-Employed Physician Assistants on a Level II Community-Based Orthopaedic Trauma System*, 27 J ORTHOPEDIC TRAUMA (Apr. 2013), at 87-91.

¹⁹ Brett E. Glotzbecker, Deborah S. Yolin-Raley, Daniel J. DeAngelo, Richard M. Stone, Robert J. Soiffer, & Edwin P. Alyea III, *Impact of Physician Assistants on the Outcomes of Patients With Acute Myelogenous Leukemia Receiving Chemotherapy in an Academic Medical Center,* J. OF ONCOLOGY PRAC. (June 2013). ("Conclusion: The data demonstrate equivalent mortality and ICU transfers, with a decrease in LOS, readmission rates, and consults for patients cared for in the PA service. This suggests that the PA service is associated with increased operational efficiency and decreased health service use without compromising health care outcomes."), available at http://jop.ascopubs.org/content/early/2013/06/11/JOP.2012.000841.abstract



Reimbursement Resources

Critical Care Services

Critical care services are defined by the Medicare program as:

A critical illness or injury acutely impairs one or more vital organ systems such that there is a high probability of imminent or life-threatening deterioration in the patient's condition. Critical care involves high complexity decision making to assess, manipulate, and support vital system functions(s) to treat single or multiple vital organ system failure and/or to prevent further life-threatening deterioration of the patient's condition.¹

Thus, critical care services are defined by the patient's condition, not their geographic location (such as a critical care/intensive care unit). Additionally, the Medicare Claims Processing Manual states:

Critical care services must be medically necessary and reasonable. Services provided that do not meet critical care services or services provided for a patient who is not critically ill or injured in accordance with the above definitions and criteria but who happens to be in a critical care, intensive care, or other specialized care unit should be reported using another appropriate E/M code (e.g., subsequent hospital care, CPT codes 99231–99233).²

Critical care payment review has come under increased scrutiny with resulting denials for increased claims error rates. National Government Services posted the following guidance on this topic:

Primary Problems Identified

- Medical necessity of critical care not supported in records Documentation often failed to support the provision of critical care by the billing provider to a critically ill patient. In these cases, the services were usually recoded to the hospital evaluation and management (E&M) service supported by the medical record. Critical care services are allowed only if both the illness/injury and the treatment being provided meet the requirements for coverage.
- Time not documented in the medical record Critical care is a timebased service and the physician's progress notes must document the total time devoted to the provision of critical care services. Noting a range of minutes is not acceptable. If the record supported that critical services were provided but the time was not documented, the service was denied for insufficient information.

¹ Medicare Claims Processing Manual, Chapter 12, *Physician/Nonphysician Practitioners*, §30.6.12" Critical Care visits and Neonatal Intensive Care (Codes 99291-99292)" available at https://www.cms.gov/Regulations-and-Guidance/Manuals/downloads/clm104c12.pdf accessed April 18, 2017.

- **Teaching physician criteria not satisfied** For time based codes such as critical care, the teaching physician must be present for the entire period of time for which the claim is submitted. Time spent by the resident, in the absence of the teaching physician, cannot be billed by the teaching physician as critical care. Only time spent by the teaching physician was considered when reviewing these services.
- Lack of acceptable signature E&M services require the signature of the performing provider. The lack of a valid signature is often found when the medical records are in an electronic format. If an acceptable signature is not present and an attestation statement is not provided in a timely manner when requested, the service is denied.
- Failure to submit documentation Failure to submit the requested documentation within 45 days from the date on the additional documentation request letter results in a denial of the service.³

Critical Care Resources

Article: Deborah Hale and Myra Wiles, "Documenting and billing for critical care services," ACP Hospitalist, March 2010, http://www.acphospitalist.org/archives/2010/03/coding.htm

Article: "99291 & 99292 CPT® Codes: A Definitive Critical Care Service Resource", The Happy Hospitalist, https://thehappyhospitalist.blogspot.com/2008/11/how-to-bill-critical-care.html

American Medical Association, CPT® Professional 2017, Critical Care Service Codes.

Article: Kristy Welker, "How to bill for critical care services", Today's Hospitalist, November 2009, http://www.todayshospitalist.com/How-to-bill-for-critical-care-services

Department of Health & Human Services, Pub 100-04 Medicare Claims Processing Centers for Medicare & Medicaid Services (CMS), Transmittal 1548: *Critical Care Visits and Neonatal Intensive Care (Codes 99291 - 99292)*, July 9, 2008. Available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1548CP.pdf

MLN Matters article MM5993: Critical Care Visits and Neonatal Intensive Care (Codes 99291 - 99292), available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM5993.pdf accessed April 18, 2017.

³ National Government Services, *Medical Review Focus Areas, Critical Care Prepayment Review Findings for Jurisdiction 6*, available at https://ngsmedicare.com/ accessed April 18, 2017.

Observation Services

"Observation" is an outpatient order: PAs and NPs can order outpatient services, including observation services, as long as they have been **granted the privileges by the facility to do so.** (Emphasis added.)

Observation services are covered only when provided by the order of a physician or another individual authorized by State licensure law and hospital staff bylaws to admit patients to the hospital **or to order outpatient tests.**⁴

Practitioners providing observation services should familiarize themselves with the specific observation CPT® codes and billing rules.^{5, 6}

Transitional Care Management

PAs and NPs are healthcare professionals authorized to provide transitional care management (TCM) services, defined as services provided to Medicare beneficiaries discharged from an inpatient setting to the community setting:⁷

Effective January 1, 2013, under the Physician Fee Schedule (PFS) Medicare pays for two CPT codes (99495 and 99496) that are used to report physician or **qualifying nonphysician practitioner** care management services for a patient following a discharge from a hospital, SNF, or CMHC stay, outpatient observation, or partial hospitalization.⁸ (Emphasis added.)

⁴ Medicare Benefit Policy Manual, Chapter 6:Hospital Services Covered Under Part B, §20.6 Outpatient Observation Services, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c06.pdf accessed April 18, 2017.

⁵ Department of Health & Human Services, Centers for Medicare & Medicaid Services, CMS Manual System Pub 100-04 Medicare Claims Processing, Transmittal 1466, Payment for Hospital Observation Services (Codes 99217 - 99220) and Observation or Inpatient Care Services (Including Admission and Discharge Services - Codes 99234 - 99236), available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1466CP.pdf accessed April 18, 2017.

⁶ MLN Matters ® MM5791: Payment for Hospital Observation Services (Codes 99217 - 99220) and Observation or Inpatient Care Services (Including Admission and Discharge Services - Codes 99234 - 99236), available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM5791.pdf accessed April 18, 2017.

Department of Health And Human Services Centers for Medicare & Medicaid Services, Medicare Learning Network®, *Transitional Care Management Services*, ICN 908628 December 2016, available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Transitional-Care-Management-Services-Fact-Sheet-ICN908628.pdf accessed April 18, 2017.

⁸ CMS.gov, Frequently Asked Questions about Billing the Medicare Physician Fee Schedule for Transitional Care Management Services, March 17, 2016. Available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/FAQ-TCMS.pdf accessed April 18, 2017.

Chronic Care Management

The Centers for Medicare & Medicaid Services (CMS) recognizes Chronic Care Management (CCM) as a critical component of primary care that contributes to better health and care for individuals...Physicians and the following non-physician practitioners may bill CCM services:

- Certified Nurse Midwives
- Clinical Nurse Specialists
- Nurse Practitioners
- Physician Assistants⁹

Notes



Notes



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