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Health Care Compliance Association
PHILADELPHIA REGIONAL ANNUAL CONFERENCE
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Top 10 Risks of Physician Compliance

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- D. Scott Jones, CHC and Richard E. Moses, DO, JD do not have any financial conflicts to disclose.
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#1: EHR Errors Can Hurt Patient Safety

- No firm data establishing EHR improves patient safety
- CRICO → evidence-based risk management group of companies owned by Harvard medical community
 - 248 medical malpractice cases w/serious unintended consequences from EHR use
 - 80% involved moderate to severe harm
 - Errors occurred in ambulatory > inpatient settings
 - Death more likely in inpatient settings
- Percentage of all IT-related malpractice cases:
 - Medication error (31%), Diagnostic error (28%), Treatment complications (31%), Other (10%)
 - 63% had user-related human factor issue v. 58% had system-related design or technology issue

www.healthdatamanagement.com/news/health-it-mistakes-can-hurt-patient-safety
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OIG: Focused on EHR since 2014

- OIG EHR "Vulnerability Report"
- Objective:
 - Describe how CMS & its contractors implemented program integrity practices in light of EHR adoption
- Concerned that EHRs may make it easier to commit fraud
- 2 Major areas where EHRs may be used to commit fraud:
 - Copy/Pasting
 - Over documentation

http://oig.irs.gov/reports/oei-04-11-00571.pdf
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EHR Meaningful Use

- OIG Work Plan 2016:
 - OIG will perform audits to determine whether electronic health information is adequately protected – a security risk analysis of certified EHR technology is required
 - See 45 CFR § 164.308(a)(1) and 45 CFR § 170.314(d)(1)-(d)(9)
 - OIG will continue review of EHR incentive payments for meaningful use, through 2016 (\$20B was paid through July 2015)
- Providers who did not meet Meaningful Use requirements saw PFS payment reductions beginning 2015
- CMS issued hardship exceptions information for 2017+

OIG Work Plan, FY2016, Appendix B, Pg. 75-76, Recovery Act Review, https://www.cms.gov/regulations-and-guidance/legislation/hincertivoprograms/payermbod_hardship.html
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Interoperability by 2018: SGR Repeal and Medical Provider Payment Modernization Act of 2015 (HR 1470)

Declares it a national objective to achieve widespread exchange of health information through interoperable certified electronic health records technology nationwide by **December 31, 2018**

https://www.congress.gov/bills/114/congress/114/house/bills/1470
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#2: Advanced Practice Providers Expanding APP Duties

- Competent to diagnose & treat at an advanced level
- Delegation and team effort allows physician/APP to deliver higher quality of care
- Physician may attend to more serious patient health care concerns
- APPs deliver less expensive treatment
- APPs improve access in underserved areas
- Promoted as a solution to the national physician shortage

Wash J4 Gastroenterology 2000;188:459-60.
Druis RS, et al. New Engl J Med 2003;348:130-7.
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Expanding APP Duties

- Discussion nationally regarding the roles APPs should play in medical care (Physician shortage, increasing numbers of insureds)
- APPs taking on duties once solely performed by physicians
 - Independent Mini Clinics (Pharmacies)
 - VHA proposal to allow NPs to practice throughout the system without physician supervision
- State Scope-of-Practice Rules differ widely on autonomy
- Rapid changes in state laws and regulations

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Regulatory Pressures to Expand APP Duties

- Increasing Patient Volumes under PPACA
- Physician Burnout and Workload
- Financial Necessity/Extender Productivity
- Financial Necessity/Cost Savings
- Institutions using APPs as:
 - Hospitalists
 - Medically Underserved Areas
 - Emergency Departments and high-volume triage roles

Hutchinson LE, Mossa RE, Jones DS. Compliance Today (January) 2016;18:42-46.
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#3: Clinical Practice Guidelines Purpose and Development

- Purpose of CPGs
 - Improve effectiveness & efficiency of medical practice
 - Standardize practice
 - Improve healthcare outcomes
- CPGs developed by professional societies, healthcare organizations, government, international organizations

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CPG Growth 1974-2011: Number of English Language References NIH Database, PubMed

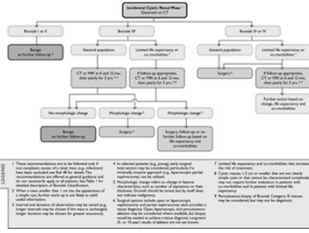


Derived from: US National Library of Medicine National Institutes of Health PubMed.gov, available at <http://www.ncbi.nlm.nih.gov/pubmed...>

Taylor C. Journal of Legal Medicine 2014;35:273-290.
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CPG Example: Incidental Renal Mass on CT Scan



Berland LL, Silverman SG, Gore RM, et al. J Am Coll Rad 2010;7:754-773.
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CPG Risk Education Resources

- General Professional Organizations
 - American College of Physicians
 - American College of Surgeons
- Specialty Organizations Examples
 - www.gi.org (American College of Gastroenterology)
 - www.gastro.org (American Gastroenterological Association)
 - www.aasld.org (American Association for the Study of Liver Disease)
- U.S. Department of Health and Human Services
 - www.guidelines.gov

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#4: Telemedicine CMS Payment for Telehealth (partial listing)

- Emergency Department Visits
- F/U consults to inpatient hospital and SNF beneficiaries
- Subsequent hospital services (1 visit every 3 days limit)
- Kidney disease education services
- Diabetes self management training services
- Behavioral assessment and intervention
- Psychotherapy
- Pharmacologic management
- ESRD services
- Annual Wellness Visit, Personalized Prevention Plan of Service (PPPS)

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/telehealthsvctcst.pdf
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Telemedicine: Stringent Rules for Physician-Patient Encounter

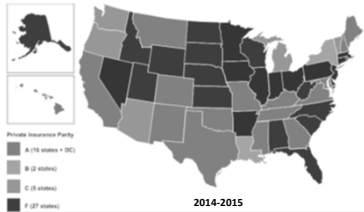
- Open: 22
- Stringent: 28
 - Plus DC



American Telemedicine Association, March 2015: State Telemedicine Gaps Analysis. www.americantelemed.org/docs/default-source/policy/50-state-telemedicine-gaps-analysis-physician-practice-standards-licensure.pdf?sfvrsn=14
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Parity Laws: Private Insurance Telemedicine Coverage



Open: 22
 Limited: 26
 Closed: 2

American Telemedicine Association, March 2015: State Telemedicine Gaps Analysis. www.americantelemed.org/docs/default-source/policy/50-state-telemedicine-gaps-analysis-physician-practice-standards-licensure.pdf?sfvrsn=14
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Telehealth Potential Risks

- Compliance with State Regulation regarding first face-to-face encounter, in state license, out of state cross border licensing requirements – these vary widely, state to state. Research state medical boards and legal code.
- Related concerns about location of patient during telehealth visit. Does out of state communication violate state regulation?
- Patient education on quality limitations of telemedicine visits.
- Telehealth Informed Consent, including impact of quality of transmission on diagnosis; alerting patient that information transmitted may not be secure.
- Referral network availability for patients requiring follow up services.
- Compliance with CMS as well as State regulations.
- PPACA and MACRA expectations regarding the growth and use of telehealth.

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#5: Social Media HIPAA/Laws & Regulations

- **Federal Legislation: HIPAA**
 - Most apparent issue regarding social media in health care
 - Standardized electronic processing of PHI
 - Do not disclose: Name, geographic subdivisions smaller than a state, date of birth, date of death, social security number, telephone number, e-mail address
- **University Medical Center Case**
 - Governor Barbour of Mississippi tweets about Legislature recognizing fiscal situation
 - Employee Carter tweets Governor should schedule his routine appointments during the week when UMC is open instead of paying overtime to 15-20 staff on a weekend
 - **ISSUE:** PHI breach v. exercise of right to free speech
 - **OUTCOME:** Employee Carter resigns

www.its.gsu
<http://www.mernews.com/story/11713365/woman-out-of-a-job-after-sending-tweet-to-governor-barbour>
<http://jama.ama-assn.org/2013/01/10/social-media-policies>
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Social Media: Laws & Regulations Medical Malpractice

- Use of social media by health care professionals affects course of litigation
- Generally, relevant social media communications & other electronic stored data must be produced
- Surgeon uses social media (Twitter) for patient education updates
 - Plaintiff uses Tweets as "statement against interest" → hearsay comes in as evidence
 - Educational video used as evidence surgeon did not meet the standard of care

www.americanbar.org/publications/Regulation_Journal/2012_13/winter/the_admissibility_social_media_evidence.html
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Social Media: Laws & Regulations Professional Ethics

- Employed physicians of health care organizations
 - Need to comply with laws and ethics rules of those organizations
 - Subject to additional levels of discipline internally
- Most state Medical Boards found violations of online professionalism
 - Inappropriate contact with patients
 - Inappropriate prescribing
 - Misrepresentation of credentials
 - Misrepresentation of clinical outcomes

Bottles K, Kim J. Physician Exec 2013;33:94-96.
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Social Media: Laws & Regulations The House Staff

- Medical student & young physician perspective on social media
 - Medical students are heavier users of social media than older physicians
 - Employed by health system/teaching institution → internal rules & risks
- Challenge: Requisite level of professionalism
 - 2009: 60% U.S. medical schools reported medical students posting inappropriate unprofessional content online

www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion10015.page
Bottles K, Kim J. P&S 2013 (September-October 16).
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#6: Electronic Communication with Providers

- Patient receives Dismissal Letter after offering female physician a Rolex watch as a gift, and making verbal advances during an office visit.
- Messages from physician to compliance officer after patient receives letter:
- **Message 1:** *He called back 50 min later and left a very verbose message - he received the dismissal letter and is asking to "reconcile" - he states he doesn't understand why I am mad at him, goes on and on like emails. I'll update if I get further messages.*
- **Message 2:** *He called a total of 4 times. Last call at 2 AM Christmas morning but no more. Documented in EMR. I didn't contact police since calls didn't continue.*

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Patient Sends Photo of Genital Anatomy to Physician e-mail

- Physician contacts compliance officer after receiving graphic photo from patient, and offers this explanation:
- *He emailed that photo overnight and called, and we spoke this morning. He verbally threatened that if he contacted a lawyer that there would be issues, especially with the insurance. He might be referring to my coding of his revision surgeries to try to get coverage for him so that he didn't need to be self pay.*
- *I did explain on the phone that I do not know why he continues to heal asymmetrically, and that the asymmetry is worse when he is relaxed in the shower (evidenced by his photo). I can only assess him in the office and based upon the photos from October 2015, although not perfect, it seemed acceptable. He is upset by how much he paid back in 2014, what he had to pay with the revisions due to his insurance and the way things look now.*

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#7: Medical Mobile APPs v. “Medical Mobile APPs”



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FDA Mobile Medical APPs Guidance



FDA Mobile Medical APPs Guidance

I. Introduction

The Food and Drug Administration (FDA) recognizes the extensive variety of actual and potential functions of mobile apps, the rapid pace of innovation in mobile apps, and the potential benefits and risks to public health represented by these apps. The **FDA is issuing this guidance document to inform manufacturers, distributors, and other entities about how the FDA intends to apply its regulatory authorities to select software applications intended for use on mobile platforms (mobile applications or “mobile apps”)**. Given the rapid expansion and broad applicability of mobile apps, the FDA is issuing this guidance document to clarify the subset of mobile apps to which the FDA intends to apply its authority.

Many mobile apps are not medical devices (meaning such mobile apps do not meet the definition of a device under section 201(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)), and FDA does not regulate them. Some mobile apps may meet the definition of a medical device but because they pose a lower risk to the public, FDA intends to exercise enforcement discretion over these devices (meaning it will not enforce requirements under the FD&C Act). The majority of mobile apps on the market at this time fit into these two categories.

Consistent with the FDA’s existing oversight approach that considers functionality rather than platform, the **FDA intends to apply its regulatory oversight to only those mobile apps that are medical devices and whose functionality could pose a risk to a patient’s safety if the mobile app were to not function as intended**. This subset of mobile apps the FDA refers to as mobile medical apps.

FDA is issuing this guidance to provide clarity and predictability for manufacturers of mobile medical apps. This document has been updated to be consistent with the guidance document entitled “Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices” issued on February 9, 2015.

Mobile Medical APPs: Potential Risks

- Technology quality
 - Interference with accuracy of diagnosis
 - Interference with accuracy of treatment
- Guidelines
 - Some exist → another developing issue
 - NB: Standard of care issue
- Hacking
- Quality measurement?
- Certification requirements?
- Training requirements?



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#8: Compliance and Malpractice

- **Government Accountability Office (GAO)**
- "...beneficiaries...who receive healthcare from providers who **adhere to PPACA**...may receive **higher quality of care**...Conversely, those who receive care from providers who fail to do so may receive **lower quality of care**."
- "...it is possible that, if these (PPACA) standards and guidelines become accepted medical practice, they could impact the standard of care **against which provider conduct is assessed in medical malpractice litigation**."

www.gao.gov/assets/590/589657.pdf

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Smile! You're on Physician Compare

- 900,000 physicians listed
- 140,000 hits/day
- CMS must allow physicians & other professionals to have reasonable opportunity to review their results through PECOS before posting
 - 30 day annual preview period for all measurement data occurred October, 2014



https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/physician-compare-initiative/Updating_and_Editing_Data_on_Physician_Compare.html
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CMS Releases Provider Billing Data

- U.S. News & World Report analysis of Medicare data (2015):
 - Dr. Gregory Sampognaro is one of the busiest interventional cardiologists in the United States. Dr. Sampognaro ranked 17th in the U.S. in 2012 in the number of diagnostic angiograms and angioplasties performed.
 - Interview with Dr. Sampognaro: "I already know that I'm one of the busiest cardiologists in the country. The reason is geography. I practice in an extremely underserved area. There are only four interventional cardiologists...I'm one of four."
 - Where does Dr. Sampognaro work?
 - Pittsburg, PA? Raleigh, NC? ~~Monroe, LA~~ Sioux Falls, SD? Las Vegas, NV? Carmel, CA?
- <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/index.html>

US News and World Report, "Are Doctors Exposing Heart Patients to Unnecessary Cardiac Procedures?" Sternberg S & Dougherty G. 2/11/15. © 2015 Medical Mutual Insurance Company of North Carolina. All rights reserved.

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The Value Based Modifier (VM): Publicly Available Quality Data

- Quality data reported under PQRS equals modification to payments under the Physician Fee Schedule (PFS)
- VM use began 2015 for groups of 100 or more; full implementation 2017
- Physician groups of 10 or more must report beginning 2016; expect all physicians to report by 2017
- Quality tier system and PFS reductions of up to 2%
- QRUR (Quality and Resource Use Reports) are issued each fall, and indicate how the value based modifier will impact individual physician reimbursement
- <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Obtain-2013-QRUR.html>

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Are you reviewing PQRS and QRUR Reports?

- 2016 PQRS Reports
 - <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/pqrs/analysisandpayment.html>
- 2016 QRUR Reports (2015 data)
 - <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Obtain-2013-QRUR.html>
- To Request a CMS QualityNet Informal Review of Incorrect VM Assessment
 - https://www.qualitynet.org/portal/server.pt/community/pqri_home/212

<https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/pqrs/analysisandpayment.html>
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#9: Physician Burnout: The Physicians Foundation

- 81% physicians overextended or at full capacity
- 44% physicians plan to reduce patient access to services
- 35% physicians independent practice owners
- 69% physicians believe their clinical autonomy is limited & their decisions compromised
- 26% physicians participate in an ACO
 - 13% of this group believe ACOs will enhance quality & decrease costs
- Physicians spend 20% of their time on non-clinical paperwork

www.physiciansfoundation.org/uploads/default/2014_Physicians_Foundation_Biennial_Physician_Survey_Report.pdf
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Physicians Speak Out: The Physicians Foundation ...and about PPACA

- 46% Physicians give PPACA grade of D or F
- 25% Physicians give PPACA grade A or B
- 39% Physicians accelerating retirement plans due to PPACA

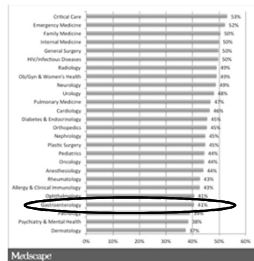
www.physiciansfoundation.org/uploads/default/2014_Physicians_Foundation_Biennial_Physician_Survey_Report.pdf
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2015 Physician Burn Out By Specialty

Burnout and Happiness in Physicians: 2013 v. 2015

Medscape Physician Lifestyle Report: 46% of all physicians responded that they had burnout, which is a substantial increase since the Medscape 2013 Lifestyle Report, in which burnout was reported in slightly under 40% of respondents.



Medscape
Pedman C. Medscape 1/26/16
www.medscape.com/viewarticle/1334327

#10: Patient Portals

- Secure online website that gives patients convenient 24 hour access to provider communication and personal health information from anywhere with an Internet connection
- Secure username and password required
- Theory is that this will improve patient outcomes

<https://www.healthit.gov/providers-professionals/faq/what-patient-portal>
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Patient Portals

- Simple Patient Portals allow viewing of:
 - Recent doctor visits, discharge summaries, medications, immunizations, allergies, lab results, et cetera
- More Advanced Patient Portals allow:
 - Exchange of secure e-mail with the health care team, request prescription refills, schedule non-urgent appointments, check benefits and coverage, update contact information, make payments, download and complete forms, view educational material

<https://www.healthit.gov/providers-professionals/faq/what-patient-portal>
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Patient Portals

- Required by HITECH
- Part of Meaningful Use 3
- Developing area of liability
- Areas of risk:
 - HIPAA data breach
 - Inappropriate use
 - Inappropriate content
 - Other evolving areas of potential risk exposure
 - Examples...

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SUMMARY & CONCLUSIONS

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