Legislative & Regulatory Roundup

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2016 Zurich Healthcare Customer Symposium
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Agenda
6-point legislative and regulatory roundup

1. Mergers and acquisitions
2. Food and Drug Administration
3. The Joint Commission
4. Telehealth/telemedicine
5. Physician issues
6. National opioid epidemic
Mergers & acquisitions
Is bigger really better?

• High-profile mergers and acquisitions likely will continue in 2016 with regulators taking center stage in the debate over how consolidation impacts consumers.

• Standard Merger and Acquisition Reviews Through Equal Rules (SMARTER) Act act **passed in House 235-171 on March 23, 2016**
  – Standardizes the merger review process for the DOJ and FTC to rely exclusively on the federal courts to determine the competitiveness of a transaction.
  – Currently, the FTC can challenge transactions under different processes and standards than the DOJ.
  – This could eliminate the FTC's ability to challenge a merger without going to court.
  – Hospitals have been adversely impacted by the ability of the FTC to use its own internal administrative process to challenge a transaction.

• **Introduced in the Senate and referred to Committee on the Judiciary on April 4, 2016**

• Bill not supported by the President

Changes in generic drug approval process

- New process for abbreviated new drug applications (ANDAs) for sole-source products or generic submissions with only one manufacturer (March 2016)
  - Expedites the approval process for medications that could be used as alternatives to drugs when there is only one approved treatment
  - ANDA submissions apply to drugs that have only one formulation approved by the FDA and no blocking patents or exclusives

- The FDA has been working to incorporate the patient perspective into the drug-approval process, especially over the past five years, under growing pressure from advocacy groups and Congress.

States’ Response
Access to treatments and devices

• Right to Try Laws
  – Modeled after the “Compassionate Use” federal policy
  – 27 states have enacted laws that allow terminally ill patients to access investigational treatments and devices that are not yet FDA approved
  – Treatments have passed Phase I, basic safety testing, with the FDA
  – Patients must exhaust all other available options
National medical device evaluation system

FDA releases preliminary recommendations – April 2016

• Response to rapid pace of new and improved technologies
• Designed to strike the right balance between **assuring safety** and **fostering device innovation and patient access**
• Help providers and patients make better informed treatment decisions
• Improve coordination & efficiencies in developing actionable evidence on safety & effectiveness across the total product lifecycle
• Apply advanced analytics to data tailored to the unique data needs and innovation cycles of medical devices.
• Link and synthesize data from:
  – clinical registries
  – electronic health records
  – medical billing claims

The Joint Commission
SE Alert Issue 56

- **Released February 2016**
- Reveals most common root cause of suicide - “shortcomings in assessment,” mainly with psychiatric assessments
- Suicide fast facts
  - 10th leading cause of death
  - claims more lives than traffic accidents and more than twice as many as homicides
- Goal to assist all healthcare organizations, providing both inpatient and outpatient care, to better identify and treat individuals with suicide ideation.
- Suggested actions for *at-risk individuals:*  
  - Suicide ideation detection  
  - Screening  
  - Risk assessment  
  - Safety  
  - Treatment  
  - D/C and Follow-up care  
  - Provider/staff education & documentation
- TJC urges all healthcare organizations to “develop clinical environment readiness by identifying, developing and integrating comprehensive behavioral health, primary care and community resources to assure continuity of care for individuals at risk for suicide.”

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1,5,6 The Joint Commission. Detecting and treating suicide ideation in all settings. Sentinel Event Alert Issue 56, 2/24/16. http://www.jointcommission.org/assets/1/6/SEA_56_Suicide_Infographic_2_10_16_FINAL.pdf
2 Centers for Disease Control and Prevention. FastStats - Mortality – All homicides.
Telehealth

Coverage update – 2016 Legislative Session

• 44 states have introduced over 150 telehealth-related bills

• Most bills address:
  – Reimbursement to private payers & Medicaid
  – Adoption of the Federation of State Medical Board’s model language for an Interstate Medical Licensure Compact

Center for Connected Health Policy. State Telehealth Laws and Medicaid Program Policies. March 2016
http://cchpca.org/sites/default/files/resources/50%20State%20FINAL%20April%202016.pdf
Telehealth
Coverage update - Medicaid

• No two states are alike in how telehealth is defined and regulated.
• 47 states have some form of Medicaid reimbursement
• Live Video is most reimbursed form of telehealth modality for Medicaid
• 16 states have some form of reimbursement for Remote Patient Monitoring (RPM) in Medicaid programs
• Limitations on type of facility that may be an originating site is more common, often excluding the home; 8 states have added more sites to their policy since July 2015.

Telehealth
Coverage update - Medicare

• Current medicare reimbursement limitations
  – Limited to rural areas
  – What qualifies as an originating site
  – Types of healthcare professionals who can provide services
  – No coverage for RPM
  – Demonstration waivers underway for participating entities and qualifying enrollees for exemption from telehealth requirements under Medicare Program.

Center for Connected Health Policy. State Telehealth Laws and Medicaid Program Policies. March 2016
http://cchpca.org/sites/default/files/resources/50%20State%20FINAL%20April%202016.pdf
Telehealth
Coverage update – private payers

- 33 states have laws that govern private payer telehealth reimbursement policies.
- Washington’s private payer law will be enacted on Jan. 1, 2017.
- Not all laws mandate reimbursement.
- Some laws require equal reimbursement irrespective of telehealth-delivered or in-person.
Telehealth update

Policy issues

• Licensure
  – Health professional must generally be licensed in state where patient receives treatment
  – 9 state medical boards issue special licenses
  – 12 states adopted the Federation of State Medical Boards Interstate Medical Licensure Compact
  – Other states make allowances for practicing in contiguous states or may issue a temporary license.

• On-line prescribing
  – Most states consider an online questionnaire to establish a relationship as inadequate.
  – Some states may require an in-person physical exam prior to writing a prescription
  – Some states allow use of telehealth to conduct the exam
Telehealth update

Policy issues

- Consent – 29 states have informed consent policies
- Credentialing and privileging
- On-line prescribing
- Medical malpractice and professional liability insurance
- Privacy and security
- Fraud and abuse
- Broadband availability
Telehealth
New White House initiative - ConnectALL

- Announced March 10, 2016
- Aim to ensure broadband parity for Americans of all income levels.
- President Obama announced a goal of providing broadband access to 20 million more Americans by 2020.
- Priority is to push the Federal Communications Commission to revitalize its current phone subsidy program by extending coverage to the internet.

Fact Sheet: President Obama Announces ConnectALL Initiative. 3/9/16 Available at: https://www.whitehouse.gov/the-press-office/2016/03/09/fact-sheet-president-obama-announces-connectall-initiative
Physician issues
Shortages – A looming crisis

- Physician shortage by 2025 (American Association of Medical Colleges)\(^1\)
  - Estimates shortage ranging between 61,700 and 94,700 doctors
  - Projected primary care shortfall by up to 35,600 physicians
  - Projected shortfalls in non-primary care specialties range between 37,400 and 60,300
  - Projected shortfalls for surgeons between 25,200 and 33,200

- Mental health provider shortage – ‘Silent Shortage’\(^2\)
  - Shrinking workforce; high demand for psych NPs
  - Health Resources and Services Administration (HRSA) designated 4K Mental Health Professional Shortage Areas based on a psychiatrist to population ratio of 1:30,000
  - Core mental health providers include psychiatrists, clinical psychologists, clinical social workers, psychiatric nurse specialists, and marriage and family therapists.

- **Drivers** – population growth and aging, expansions in coverage, physician retirement, physician burnout, increase in hospital consolidations and practice acquisitions

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Response to shortage

- Resident Physician Shortage Act of 2015 (S. 1148/H.R. 2124)\(^1\)
  - Limits on the number of Medicare-funded residency training slots constrain the ability of hospitals to train new physicians
  - Would add 15,000 residency positions eligible for GME and IME
  - About a 15 percent increase in residency slots---lifts the cap of residency slots set at 1996 levels
  - **Introduced in House; in Senate, referred Finance Committee on 4/30/2015**

- Locum tenens?\(^2\)
  - Increase in physicians choosing temporary staffing firms
  - More growth in staffing industry

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\(^1\)https://www.congress.gov/bill/114th-congress/house-bill/2124

\(^2\)Flanagan, N. How temporary physicians may buoy the nation’s physician shortage. Healthcare Dive. 4/23/16
Concurrent surgery
Is it all right for a surgeon to operate on more than one patient at the same time?

- Not a new issue
- Series of Boston Globe articles raised visibility
- Highlighted Massachusetts General Hospital (MGH)
- Focused on complex spine surgery case with a complication of sudden paralysis (known risk)
Senate Finance Committee

Inquiry on concurrent surgery

• Led by Senator Orrin G. Hatch, a Utah Republican who heads the Finance Committee; oversees federal health programs
  – Information request of 20 hospital systems for the total number of “concurrent surgeries,” broken down by specialty, at each hospital from 2011 to 2015, and policies about whether patients are informed beforehand (February 2016)
  – “Concern about reports of patients not being informed that they may be sharing their surgeon with another patient, and we are especially concerned by reports that, in some cases, steps have been taken to actively conceal this practice from patients.” (Senator Hatch)
Any evidence of harm?

• MGH - analysis of hundreds of surgical cases and also 25 cases of concurrent surgeries where patients suffered complications. “MGH concluded that none of the injuries was the result of double-booking, but the hospital declined to provide details to the Globe.”

• Doctors Company – no indication of a correlation. “A review of 7,330 surgery malpractices in the company’s database from the past eight years found no mention of concurrent surgery as a factor”
Potential benefits of concurrent

- “Double-booking” allows hospitals to reduce wait times
- Give residents graduated responsibility for components of surgeries - builds their skill and experience
- Helps manage flow during times of emergency or urgent cases
- Increase patient access to sought-after surgeons or those with expertise in highly specialized procedures
- Routine aspects of operation do not require expertise of experienced surgeons
Cases – Whistle blower, false claims

• Physicians alleging surgeons running multiple operating rooms simultaneously and leaving residents to do critical parts of operations unsupervised.
  – Vanderbilt – suit pending
  – Rush –$2.1 million out of court settlement
  – Barnes-Jewish Hospital – case tossed by court

• Pennsylvania Hospital – false claims suit
  – MD paid $1.89 million. Denied allegations and said he failed to document appropriately

Cases – medical malpractice

- Brigham and Women’s Hospital – alleged surgeon allowed others to perform surgery that had serious complications. Court did not allow the issue into trial. Jury verdict for MD, but appeals court granted new trial.

- Cleveland Clinic – Accused surgeon of overlapping cases. Hospital denied this was the case. Case dismissed, being appealed.

- UCLA, Santa Monica Medical Center – two spine cases started within minutes of one another, one had complications. Suit pending.

Framing the issue...

- Can/should a surgeon conduct/oversee more than one surgical procedure at the same time?

- Current practices reflect CMS requirements
  - Surgeons allowed to perform concurrent operations but required to be present for the “critical or key portions” of each surgery
  - Nothing specifically addresses “immediate availability” of surgeon
Concurrent surgeries
American College of Surgeons Statement of Principles

• Released April 12, 2016

• ACS states: “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 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 as being immediately available.”

• Emphasizes the surgeon’s primary role
American College of Surgeons
Definitions

• **“Critical” or “key” portions of an operation** - The “critical” or “key” portions of an operation are those segments of the operation when essential technical expertise and surgical judgment are required in order 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 should be defined more completely by the local institution.

• **Primary Attending Surgeon** - Surgical attending of record or the principal surgeon involved in a specific operation.

• **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.

• **Physically Present** - Located in the same room as the patient.

American College of Surgeons, Statement of Principles
https://www.facs.org/about-acs/statements/stonprin#anchor172771
HHS/SAMHSA proposed rule
Confidentiality of substance use disorder patient records

• Released February 9, 2016
• Addresses changes to the Confidentiality of Alcohol and Drug Abuse Patient Records regulations, 42 CFR part 2.
• Call for updates
  – Last substantive update was in 1987
  – Support new models of care delivery that require information sharing to support care coordination
  – Facilitate information exchange while addressing the legitimate privacy concerns of patients seeking treatment for a substance use disorder.
  – Privacy concerns include: the potential for loss of employment, loss of housing, loss of child custody, discrimination by medical professionals and insurers, arrest, prosecution, and incarceration.
• Comment period closed April 11, 2016

Comprehensive Addiction and Recovery Act (S.524)

- Bipartisan legislation to address the nation’s opioid epidemic
- **Passed in Senate 94-1 on March 10, 2016**
- Key features:
  - Availability of naloxone to law enforcement agencies and first responders and requisite training
  - Expand disposal sites for unwanted prescription medications
  - Expand best practices of evidence-based opioid and heroin treatment programs
  - Medication assisted treatment demonstration program
  - Strengthen prescription drug monitoring programs
- **As of March 14, 2016 in the House on the floor for consideration**

https://www.govtrack.us/congress/bills/114/s524
https://www.congress.gov/114/bills/s524/BILLS-114s524is.pdf
HHS awards grants

Treatment for opioid use disorders

- HHS awards $94M in grants from Affordable Care Act funding to 271 health centers in 45 states, the District of Columbia and Puerto Rico (March 11, 2016)

- Expand substance abuse services in health centers

- Focus on treating opioid use disorders in underserved populations

CDC opioid guidelines for chronic pain

• **Released March 15, 2016**

• **Scope:**
  – patients 18 and older in primary care settings
  – chronic pain defined as “lasting longer than 3 months or past the time of normal tissue healing outside of active cancer treatment, palliative care, and end-of-life care.”

• **Clinical practices addressed**
  – When to initiate or continue opioids
  – Opioid selection, dosage, duration, follow-up, and discontinuation
  – Assessing risk and addressing harms of opioid use

• **What providers should do:**
  – **Use nonopioid therapies**
  – **Start low and go slow**
  – **Follow-up**
  – **Review PDMP**
  – **Avoid concurrent prescribing**
  – **Offer treatment for opioid use disorder**

Mental Health Reform Act of 2016 (S.2680)

• Bill introduced and referred to the Committee on Health, Education, Labor, and Pensions **for consideration on March 16, 2016**

• Key features:
  - More inter-departmental coordination within Substance Abuse and Mental Health Services Administration (SAMHSA) of mental illness and substance use disorders.
  - Grant programs to promote the integration of primary and behavioral health care.
  - Re-authorize National Suicide Prevention Lifeline program
  - *Clarify appropriate use and disclosure of protected health information under HIPAA and providing resources and training on requirements for communication between providers, patients and families.*
HHS national pain strategy
Initiative to address the opioid epidemic

- Released March 18, 2016
- Outlines a roadmap for providing all patients "appropriate, high-quality and evidence-based care for pain.
- 1st coordinated plan to reduce the burden and prevalence of chronic pain and to improve the treatment of pain
- The pain strategy includes recommendations for improving pain care in six areas:
  - population research
  - prevention and care disparities
  - service delivery and payment
  - professional education and training
  - public education and communication
- CDC Guidelines for prescribing opioids for chronic pain is part of National Pain Strategy

DHHS proposed rule
Raising physician prescribing limit for opioid MAT

- **Released March 29, 2016**
- Proposed change would allow qualified physicians to prescribe buprenorphine, an FDA-approved drug used as part of medication assisted treatment (MAT), to more patients.
- **Current regulation**
  - Prescribe buprenorphine for MAT up to 30 patients initially, then after one year can request to prescribe up to a max of 100 patients
- If adopted, may prescribe up to 200 patients if they have maintained an active waiver to treat up to 100 patients for a year and have subspecialty board certification in addiction medicine or addiction psychiatry, or practice in a qualified practice setting as defined in the rule.
- The rule also would allow practitioners with a 100-patient limit to request to serve up to 200 patients for up to six months in an emergency.
- **Open for public comment through June 30, 2016**

Mental Health Parity and Addiction Equity Act (MHPAEA)

- The Mental Health Parity and Addiction Equity Act (MHPAEA) of 2008 requires health insurers and group health plans to provide the same level of benefits for mental and/or substance use treatment and services that they do for medical/surgical care.
  - The final regulations didn’t apply to Medicaid and the Children’s Health Insurance Program (CHIP)

- CMS issued a final rule on March 30, 2016 applying changes to Medicaid and CHIP, preventing inequity between beneficiaries who have mental health or substance use disorder conditions.
  - Important step in bringing Medicaid MCOs, Alternative benefit programs (ABPs), and CHIP into compliance with parity standards

- Parity applies to:
  - Intermediate levels of care (residential or intensive OP settings)
  - All plan standards

http://www.samhsa.gov/health-financing/implementation-mental-health-parity-addiction-equity-act
Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (S. 483)

• Became Law on April 19, 2016
• Addresses drug abuse and drug access
  – patients should have access to their prescriptions; not those who would abuse them
• Tackles the problem of prescription drug abuse by:
  1) clarifying penalties for manufacturing or dispensing outside approved procedures
  2) helping to ensure that supply chains to legitimate users remain intact
• The Controlled Substances Act lacks clarity on factors the DEA should consider when deciding whether to register a company applying to manufacture or distribute prescription drugs. The bill directs the DEA to use findings compiled by Congress to define those factors.
• Describes circumstances under which the Attorney General can suspend a company’s registration.
House subcommittee approves opioid bills

- The House Energy and Commerce Health Subcommittee approved **(12) Bills on April 20, 2016** to help address the opioid and drug abuse crisis.

- **Key Bill features:**
  - neonatal abstinence syndrome and tx
  - co-prescribing opioid reversal drugs
  - residential tx for pregnant and postpartum women
  - prohibit selling drugs w/dextromethorphan to minors
  - teen athletes w/opioid risks; naloxone standing orders
  - education for prescribers of extended release & long-acting opioids
  - amendment to the Controlled Substances Act to expand access to medication-assisted treatment

Additional resources


- CDC Guideline for Prescribing Opioids for Chronic Pain *Clinical Tools*. Available at: http://www.cdc.gov/drugoverdose/prescribing/resources.html

- The Joint Commission. Detecting and treating suicide ideation in all settings. Sentinel Event Alert, Issue 56. Infographic available at: http://www.jointcommission.org/assets/1/6/SEA_56_Suicide_Infographic_2_10_16_FINAL.pdf
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