M. The Nuts and Bolts of Launching and Growing a Telemedicine Program

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THE NUTS AND BOLTS OF BUILDING AND GROWING A TELEMEDICINE PROGRAM

AHLA Hospitals and Physicians Institute
February 5-7, 2014

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Welcome

• Having a Plan
• The Practitioners
• The Equipment
• The Patients
• Getting Paid
• Questions
HAVING A PLAN
Defining Telemedicine, Setting Your Services and Service Areas

Strategic Planning

- Telemedicine not just another service
- Telemedicine a modality to deliver many types of services
- Strategic because:
  - A tool to determine where and how to provide services
  - An alternative to brick and mortar
  - Full service delivery or used to supplement services already in place
Strategic Planning

• Strategic planning requires:
  • Assessment of relevant markets and environment
  • Understanding of competition
  • Determine reasons such as mission and values
• Important for counsel to “be at the table” early in the planning process
• Requires an understanding of strategic elements of telemedicine AND the underlying legal issues
• Consider Exit Strategies

Does Your Plan Look Like This?
Reasons For The Growth Of Telemedicine

• Advances in technology
• Academic medical centers asked to assist other hospitals
• Mission driven-hospitals seek to assist their communities
• Physician shortage, especially in rural areas
• Aging patient population and an increase of patients with chronic diseases
• Current regulatory environment with an emphasis on care coordination and shifting care settings
• Global health care

So Many Terms . . .

Are the following “telemedicine”?

• Telehealth
• Virtual Care
• mHealth
• Social Media
Expanding Services

- Telemedicine
- Videoconferencing
- Transmission of Still Images
- E-health and Patient Portals
- e-Prescribing
- Nursing Call Centers
- Remote Monitoring

Expanding Settings

Variety of practice settings – you need to pick your setting

- Academic medical centers (AMCs)
- Large hospital systems
- Health care clinics
- Ambulatory Surgery Centers (ASCs)
- In the home
Expanding Technology

Technology changes drive expansion and access to telemedicine, even globally

The future?

• Making the case for government resources and common standards
• Health care reform, integration and ACOs
• Emerging technologies and the next frontier
Common Themes

**Opportunities**
- Improved outcomes
- Cost efficiency
- Patient satisfaction
- Market advantage
- Affiliation rather than consolidation

**Potential Pitfalls**
- Connectivity issues
- Fraud and abuse issues
- Reimbursement
- Remedial measures and credentialing
- HIPAA privacy and security

Operational Issues Drive Legal Issues

**Defining the “Service”**
- Consults
- Call coverage
- Professional services

**Staff**
- Not just clinical staff
- Examples: IT, scheduling personal

**Equipment**
- Maintenance
- Downtimes
- Replacements
- Warranties
- Costs

**Space**
- Designated location
- Description
- Mobile
- Leases
Overview

- The CMS Condition of Participation (CoP) on Telemedicine Credentialing
- Written Agreement
- Accreditation
- Governance
- Medical Staff
- Licensure
Credentialing

• **Hospital Condition of Participation:** Both Hospitals and CAH are permitted to rely upon the credentialing and privileging Decisions made by the distant-site hospitals or distant-site telemedicine entity

• **Effective Date:** July 5, 2011

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The Joint Commission’s Reaction

“The Joint Commission is very pleased that CMS has revised its telemedicine requirements to provide more flexibility to hospitals and lessen their regulatory burden. This is an especially positive step for improving access to care for patients in rural areas. Of particular importance is the fact that critical access hospitals will have additional avenues to benefit from the services of particularly skilled physicians and practitioners.”

Mark Chassin, MD, FACP, MPP, MPH

May 6, 2011
Accreditation

• “Privileging by proxy” for all TJC-accredited hospitals and CAHs
• Standards: LD.04.03.09, MS.13.01.01 and MS.01.01.01
• Goals of TJC Standard
  • Eliminate duplicative credentialing
  • Concerns over impeding patient access to health care services
• Many agreements already in place under the TJC standards

Written Agreement - Hospital

The Governing Body of the distant site hospital will meet the requirements of CoP regarding the distant site physician providing services

The distant site hospital is Medicare certified

The distant-site practitioner is privileged at the distant-site hospital as evidenced by a current list of the practitioner’s privileges provided by the distant-site hospital

The distant-site physician holds a license issued or recognized by the State in which the hospital whose patients are receiving the telemedicine services is located

The hospital that credentials and privileges the distant-site practitioners shares the practitioner’s performance review information with the distant-site hospital
Governance

- Board Bylaws
- Medical Staff Bylaws
- Education for Board on its role and what it is delegating
- Provisions and approval of Agreement with distant site hospital or distance site telemedicine entity

Medical Staff: Bylaws

- Require revision to hospital bylaws
  - Address any aspect of Bylaws or policies that involve the physical presence of a physician
    - Meeting requirements
    - Definition of patient encounters or contacts
    - Minimum number of contacts or encounters
    - Emergency room coverage
  - Describe process and information being relied upon
Medical Staff

- Medical Staff Policies
  - Physician Health
  - Corrective Action
  - Fair Hearing
  - Disruptive Behavior
  - Patient Consent
- Impact on:
  - Department Chiefs
  - Credentials Committee
  - Medical Executive Committee
- Required to monitor quality and risk for distant site practitioner
  - Bylaws, policies or rule changes to describe process
  - How to effectively do so?
  - Communications with Distance Site Telemedicine Entity

Licensing

- State licensing varies by state:
  - Separate telemedicine license
  - Consultations
  - Full licensure needed
- The future?
  - Compact licensing
  - National licensing
  - International
THE EQUIPMENT
Fraud and Abuse, HIPAA and Vendor Agreements

Telemedicine Vendors

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<thead>
<tr>
<th>Selection Process</th>
<th>Contracts with Vendors</th>
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Early OIG Opinions

• **OIG 99-14** involved a health system that was operating a telehealth network pursuant to a federal grant, but that wanted to develop, operate, administer and fund the network after the grant had expired. The OIG determined that the arrangement would benefit physicians with subsidized line charges, free equipment and additional opportunities to earn fees, but that such remuneration was outweighed by the fact that the arrangement furthered congressional intent to promote telehealth networks in rural communities (thus improved access and decreased costs).

• **OIG 04-07** involved an arrangement where health system physicians would provide free telemedicine consultations at no charge for school-based clinics in low-income rural areas. OIG felt that the provision of non-reimbursable screening services that were not tied to reimbursable services would not violate the federal prohibition on inducements.

OIG Advisory Opinion 11-12

• OIG Advisory Opinion 11-12 (issued August 29, 2011) in which the OIG stated that it would not impose administrative sanctions where a Hub Hospital, at its own expense, provided the following to certain community hospitals in the Hub Hospital’s service area:
  • Neuro-emergency telemedicine technology
  • Neuro-emergency clinical consultations
  • Acceptance of neuro-emergency transfers
  • Neuro-emergency clinical protocols, tracking and medical education

• Stated purposes of the arrangement were to:
  • reduce mortality and morbidity rates of stroke in Hub Hospital’s metropolitan area, and
  • to lower costs associated with transfer of stroke cases that could be managed at local community hospitals.
OIG Advisory Opinion 11-12

• Agreement between the Hub Hospital and the community “Spoke Hospitals” stated that Hub Hospital would provide equipment and services, and in return Spoke Hospitals would agree not to participate in any other neuro-emergency telemedicine service without Hub Hospital’s prior approval.

• Neither the continued transfer of stroke patients to the Hub Hospital nor the value or volume of any other business generated between the parties would be a condition of participation in the arrangement.

• Neither the Hub Hospital nor the Spoke Hospital would bill any patient or third-party payor for the cost of the telemedicine technology.

OIG stated that this arrangement implicated the Anti-Kickback Statute, and that the safe harbor for personal services and management contracts was not applicable because use of the telemedicine program would be on an as-needed basis. In order to have safe harbor protection, an agreement for services to be provided on a periodic or sporadic basis must specify the schedule of such intervals, their precise length and the exact charge for such intervals.
OIG Advisory Opinion 11-12

• The OIG concluded it would not subject Hub Hospital to administrative sanctions based on the following:
  − Hub Hospital would be unlikely to generate appreciable referrals as there was no requirement or encouragement to refer patients to Hub Hospital.
  − Neither the volume or value of the Spoke Hospital’s previous or anticipated referrals, nor the volume or value of any other business generated between the parties would be a condition of participation in the arrangement.
  − Primary beneficiaries of the proposed arrangement would be the stroke patients treated at the Spoke Hospitals through telemedicine. Such treatment would be more timely and effective through telemedicine than transferring these patients to Hub Hospital.

OIG Advisory Opinion 11-12

• Additional rationale behind OIG decision:
  • Neither the Hub Hospital nor any of the Spoke Hospitals would be required to engage in any marketing activities, and each party would be responsible for the costs associated with its own marketing.
  • The telemedicine program was unlikely to result in increased costs to the federal healthcare programs because few, if any, of the consultations would be billable to Medicare. Also, the program was designed to reduce the volume of transfers of stroke patients to Hub Hospital, and thus reduce the costs associated with such transfers.
HIPAA

• Security (first and foremost)
• Privacy Rule
• Breaches and Penalties
• Business Associates

HIPAA: Security Rule

• Ensure the integrity, confidentiality and availability of the information
• Protect against any reasonably anticipated threats or hazards to security or integrity of the information
• Protect against any unauthorized use or disclosure of the information (encryption/firewalls)
• Maintain reasonable and appropriate administrative, physical and technical safeguards
• Identify a Security Official (separate from a Privacy Official)
• Ensure compliance by and training of your workforce
• Establish formal policies and develop a Security Plan (use HIPAA Security Standards as a Table of Contents for the Plan)
• Conduct frequent risk assessments of potential vulnerabilities (NIST)
• Use a unified security approach with built-in redundancies
• Controls over access to electronic records (passwords, ex-employees)
HIPAA: Business Associates

- Responsibility of Covered Entities
  - Old exception ("not my brother’s keeper") gone; now responsibility per federal common law of agency
  - Federal common law of agency
- No bright line – facts & circumstances
- Contract language important, but not controlling—totality of actual circumstances
- Terms/labels used (independent contractor) not controlling
- Per OCR, the essential factor is the right or authority to control the BA's conduct in the course of performing BA services or functions

HIPAA: Breach Notification

Nature & extent of PHI Involved
- More sensitive info?
  - Clinical (type of service, amount of detail)
  - Financial (credit card number, SSN)
- Amount of PHI involved
- Determine probability that recipient could use info in a way adverse to the patient

The unauthorized person who used the PHI or to whom the disclosure was made
- To person known to patient?
- To BA? CE?
- To someone able to re-identify?

Whether the PHI actually was acquired or viewed
- Forensic analysis may be needed
- Opened mail means actual viewing
The extent to which the risk to the PHI has been mitigated
- Assurances received of destruction and/or no further use/disclosure? Some Dignity Health facilities have attestation forms
- Are assurances sufficient?
Other factors may be considered
THE PATIENTS

Insurance, Medical Records and Consents

Medical Records

- Documentation
- Transfers between care settings
- Connectivity with EHR
- Maintenance of records
HIPAA: Electronic Access

- Patients now have right to electronic access to electronic PHI in designated record sets (for self and third party)
- The right extends to all portions of the designated record set ("may need to invest in order to meet the requirements")
- Cover Entities may:
  - Require a written request
  - Produce the record in the format requested if "readily producible" or in agreed-upon format, if not
  - Charge a cost-based fee, which includes the cost of labor to copy the electronic record, supplies for format requested, and postage if mailing is requested

Informed Consent

- May be required by state law
- Risk management reasons for consents
- Content of consent may be depending on services line
Insurance and Liability

• Check current policies
  • Professional liability coverage
  • Directors and Officers (D&O) coverage
  • Cyberinsurance
• Policies, clinical protocols and education
• Indemnification
• Standard of Care
• Consent Issues

GETTING PAID
Reimbursement for Telemedicine Services and Getting Your Brand Out There
Reimbursement

- Limited reimbursement
- Medicare
- Medicaid
- Commercial payors
- Movement under certain state law

Marketing Costs

- Look to OIG opinion
- Each paid their own cost of marketing
- Determined by lack of reimbursement
- FMV
We Are At a Cross Road

More Questions? Contact Us.

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