Health Care Reform & Clinical Trials Billing

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SWOG
October 13, 2011
San Antonio, TX

Goals

- What is the current state of reimbursement of cancer clinical trials?
- What is the impact of the Affordable Care Act?
- What are the ongoing risks which need to be managed?

The current state of cancer clinical trial reimbursement

- "HHS National Health Expenditures Projections 2009-2019" (Sept 2010)
- Projected total U.S. spending on health care services:
  - 2012: $2.85 trillion
  - 2017: $4.04 trillion
- Federal & State health care expenditure projection:
  - 2012: $1.445 trillion (124 million covered persons)
  - 2017: $2.038 trillion (153 million covered persons)
The State of Reimbursement

- **Government Payors:**
  - Medicare
  - Medicaid
- **Commercial Payors:**
  - State legislation
  - Contracts with payors
- **Employers:**
  - ERISA
  - Affordable Care Act: 2014

Medicare

- Federal program that is administered by local contractors

To determine coverage, providers must look to:
- Federal rules from CMS; and
- Local rules from “Contractor”

Medicare Clinical Research Coverage

- Medicare requires a **three-part process** for clinical research services coverage:
  1. Does the study “qualify” for coverage?
  2. What items and services are “routine costs”?
  3. Do Medicare rules allow coverage of specific “routine costs” within a research study?

- **Plus:**
  1. What is paid for by the sponsor?
  2. What is promised free in informed consent?
**Medicaid**

- Federal program administered by the individual States
- Federal rules do not speak to research
- State Medicaid Programs can enact policies as they determine

**State Legislation**

- 26 States require commercial insurance to pay for some portion of clinical trial services
- Each State has a different configuration of what it requires insurance to pay
- Some States focus on cancer clinical trials, some on pediatrics, some on phase of the study

**States: Many are limited to cancer**

- **Arizona**: Phase I-IV cancer clinical trials in which “no clearly superior non-investigational treatment exists”
- **Georgia**: Phase II-III of pediatric cancer clinical trials, but note private agreements among payors organized by the “Georgia Cancer Coalition”
- **North Carolina**: Phase II-IV of clinical trials treating a life-threatening condition
No State law or rule?

- Matter of contract law
- Review contracts with commercial insurers
- Does the insurer have a policy?
- Will "medical necessity" clause work?
- Place commercial insurers on notice
- Incorporate clinical research into renewal negotiations

Implications of State Laws

- Know all the various rules applying to your institution before budgeting
- Lead institutions in multi-site studies must understand the sub-contracting site's reimbursement landscape

What to do with insurance companies that will not reimburse?

- Point out Medicare's rules
- Negotiate into managed care agreement similar coverage as Medicare
- Use pre-authorization process to educate insurers and work through issues on an insurer-by-insurer basis
Affordable Care Act

- Section 10103 requires coverage of cancer clinical trials for certain health insurance plans
- Effective January 1, 2014
- First...an up to the minute status of the Affordable Care Act

Some terms

- Qualified individual
- Approved clinical trial
- Routine patient costs

Plans covered by ACA 10103

- “If a group health plan or a health insurance issuer offering group or individual health insurance coverage provides coverage to a qualified individual, then such plan or issuer.”
Who is a qualified individual?

"the term 'qualified individual' means an individual who is a participant or beneficiary in a health plan or with coverage described in subsection (a)(1) and who meets the following conditions:

'(1) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or other life-threatening disease or condition..."
What is covered?

- “Routine patient costs”
- "routine patient costs include all items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a qualified individual who is not enrolled in a clinical trial."

What is not covered?

- "(i) the investigational item, device, or service, itself;
- "(ii) items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; or
- "(iii) a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis."

Challenges

- Not consistent with Medicare rules
- Does not apply to Medicaid
- "Life-threatening" is not defined well
- Dubious constitutional status (though this part is unlikely to be challenged)
Aside from confusion about the application of the Affordable Care Act’s provisions, it does disturb basic risks associated with managing clinical research billing compliance:

- Coordination of the study documents
- Communication of what is billable and not billable
- Need for clarity in study documents

Ignoring clinical research billing rules can lead to:

1. Billing for services that are already paid by the sponsor (double billing)
2. Billing for services promised free in the informed consent
3. Billing for services that are for research purposes only
4. Billing for services that are part of a non-qualifying clinical trial

Coordination of basic study documents

Assemble information into “Medicare coverage analysis” or “billing grid” or “billing plan”

Determine way to direct non-covered charges to study fund and not to subject’s insurer
Managing the Information: Hypothetical MCA

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M=Medicare  
S=Sponsor  
ICF=Free in Informed Consent  
NB=Not billable to Medicare

Clinical Research Billing Process Flow

Accountable Office

Key Components of a Compliance CRB Process

- Coordination  
  - Working together  
  - Team effort  
  - No single person is responsible for everything

- Communication  
  - Exchange information  
  - Access to documents  
  - Transparency of study documents within process

- Collaboration  
  - Listening to others  
  - Working through past terminology hurdles  
  - Openness to learn  
  - Patience
A Dose of Reality

- This isn't going to happen overnight
- Try piloting ideas for clinical research claims management
- Do not be afraid to re-think plan after results of piloting
- Personal Observation: I have yet to see a clinical research billing process which after 1 year looks the same as its roll-out

Achieving Compliance

- Themes:
  - Coordination of study information
  - Communication of study information
  - Collaboration among stakeholders

Questions?