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Beyond the Cover Story Part 2: The Final ACO Regulations

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Meet Today's Speakers

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What Guidance is Available?

- CMS
  - ACO final rule
- CMS and OIG
  - Fraud and abuse interim final rule
- FTC and DOJ
  - Antitrust statement
- IRS
  - Tax exempt hospital and health care organization notice

What is an ACO?

- Eligible participants
- 5,000 Beneficiaries
- TIN
- Legal entity
- Shared savings/losses
- Quality measures

What is an ACO?

- Eligible Participants
  - Professionals in a group practice
  - Network of individual practices
  - Partnership or JV between hospitals and professionals
  - Hospital employing professionals
  - Critical access hospitals
  - **NEW: Federal Qualified Health Centers**
  - **NEW: Rural Health Centers**

What is an ACO?

- New to the definition of *eligible professional*:
  - Physician assistant
  - Nurse practitioner
  - Critical nurses specialist

Application

- Documentation
  - Relationship (*e.g.*, employment agreements)
  - Quality assurance program
  - Quality process
  - Organizational and management structure
  - Governing body
  - Compliance plan
  - Formation

Application

- Exceptions to governing body and leadership
- Shared savings
  - Track 1 or Track 2
  - Sharing of savings
  - Repay losses
- Certification
- ACO includes a FQHC or RHC – additional documents needed

Application

- Evaluation
  - Based on application
  - Must be complete
- Notice
  - CMS will notify if approved or denied
  - If denied – reason will be provided

Agreement

- Two effective dates for 2012
  - April 1, 2012 – 21 month performance period
  - July 1, 2012 – 18 month performance period
- 2013 and beyond
  - January 1st start dates – 3 year terms

Agreement

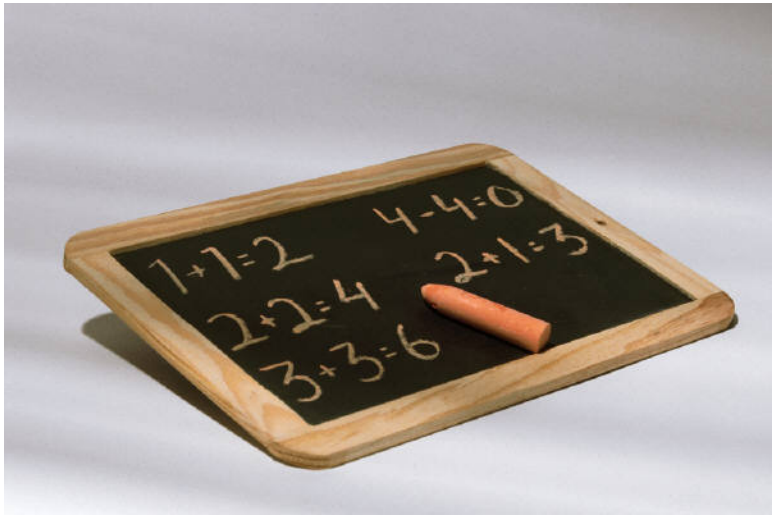
- CMS will not change:
  - Eligibility requirements
  - Calculation of sharing rate
  - Beneficiary rates
- Everything else up for grabs
  - Quality included
  - Supplement application

Agreement

- Termination
  - Great news - No 25% withholding
  - 60 day out
  - Not managed care
  - CMS may terminate
  - Mutual termination

Agreement

- Adding and subtracting ACO Participants and ACO Suppliers/Providers
  - 30 days notice to CMS
  - May change benchmarks, risk scores and preliminary prospective assignment
- "Significant change"
  - 30 days notice to CMS



Governance

- ACO must maintain a separate, identifiable governing body with authority to execute the functions of the ACO
  - Defined process to promote evidenced-based medicine and patient engagement
  - Establishing, reporting and ensuring compliance with quality standards
  - Coordinate care
  - Receiving and distributing savings
  - Repaying losses (TO CMS)

Governance

- Form of legal entity – look to state law
  - Corporation
  - Partnership
  - Limited liability company
  - Foundation

Governance

- TINs
  - Collected for all ACP participants who must have Medicare agreement
  - ACO required to report to CMS ACO participant's TINs and the NPIs of ACO providers/suppliers
  - ACO participant TIN upon which beneficiary assignment is based is exclusive to one ACO
- New vs. existing entity
  - Requirement for an independent governing body in either case
  - ACO formed by 2 or more entities must form a new entity

Governance

- Governing bodies must have the following characteristics:
  - Oversight
  - Transparency
  - Fiduciary Duty
  - Conflict of Interest policy
  - Composition and Control

Governance

- Composition and Control
  - ACO participants - 75 percent control of the governing body
    - ACO will remain provider-driven
    - Exception: Waiver request with explanation
      - Innovative ways to involve ACO participants in governance
      - Provide meaningful representation in ACO governance by beneficiaries
    - Proportionate representation on governing body not required
    - Replaced by “meaningful participation” for ACO participants

Governance

- Composition and Control
  - Medicare beneficiaries served by the ACO and representatives of entities that are not enrolled in Medicare constitute remaining 25 percent
  - Medicare beneficiary a member of governing body
  - Conflict of Interest policy
    - To ensure that members of the governing body act in the best interests of the ACO and Medicare beneficiaries
    - Disclosure of relevant financial interests
    - Procedure to determine existence of conflict and a process to resolve conflict, including remedial action

Leadership

- Manager
  - Accountable executive
  - Reports to governing body
  - Removal by governing body
  - Demonstrated ability to influence or direct clinical practice to improve efficiency processes and outcomes
- Compliance Officer
  - Reports to governing body
  - Not the attorney
  - Compliance plan
- Medical director
  - Board Certified
  - Licensed in one state in which ACO operates
  - Senior level
  - No longer physically present, but at one ACO
  - No longer full-time

Leadership

- May request approval of alternative management structure
- Describe how the alternative leadership and management structure will be capable of accomplishing the goals of the ACO

Two Shared Savings Models

- One-sided model
  - No downside risk
  - Share in up to 50% of savings
  - Performance payment limit of 10% of benchmark expenditures
  - First dollar savings
- Two-sided model
  - Downside risk
  - Share in up to 60% of savings
  - Performance payment limit of 15% of benchmark expenditures
  - First dollar savings

Shared Savings Payments

- All ACOs will be in two-sided model after the initial agreement period expires
- ACO with net loss in initial agreement period
  - Can reapply to be an ACO
  - Must identify the cause of the net loss
  - Must specify safeguards in place to achieve savings in next agreement period

Shared Savings Payments

- Eligibility for Shared Savings - Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for parts A and B services must be below the benchmark by at least the minimum savings rate (MSR) for the ACO
  - Benchmark is the estimate of what Medicare would have paid for the care of the ACO beneficiaries without the ACO

Shared Savings Payments

- MSR for one-sided model ACO is between 2% and 3.9% (depending on number of beneficiaries) and is 2% for all two-sided model ACOs
- Payment of savings is contingent on meeting quality scores in ACO participation agreement
- Benchmark is reset at the start of each agreement period

Appeals

- No review of any kind for most determinations related to ACOs and shared savings
- Limited reconsideration review by CMS
  - denials of an ACO application
  - termination for other than failure to meet quality performance standards

Assignment of Beneficiaries

- Know your beneficiaries
  - Beneficiary assignment drives benchmarks
  - Beneficiary assignment determines eligibility for Medicare Shared Savings Program (MSSP) payments

Assignment of Beneficiaries

- Beneficiary freedom of choice
  - Alignment versus assignment
- Overview of assignment methodology
  - Plurality of primary care services received
    - Defined by CPT codes
  - Prospective beneficiary assignment
    - Preliminary list at start of performance period
    - Quarterly updates
    - Final assignment based on actual treatment

Assignment of Beneficiaries

- Step-wise approach to beneficiary assignment
  - Step 1 - Beneficiary received a primary care service from a primary care physician enrolled in an ACO
    - Beneficiary is assigned to the ACO where the plurality of primary care services provided by primary care physicians were received

Assignment of Beneficiaries

- Step-wise approach to beneficiary assignment
  - Step 2 - Beneficiary did NOT receive a primary care service from a primary care physician
    - Only assigned to an ACO if s/he received at least one primary care service from an ACO physician (regardless of specialty)
    - Assigned to ACO where plurality of primary care services provided by physician or non-physician practitioners were received

Fraud and Abuse

- Waivers – CMS and OIG Interim Final Rule
  - 5 separate fraud and abuse waivers that may be used by entities participating in MSSP
  - Satisfying a waiver provides protection from
    - Stark self-referral law
    - Anti-kickback law
    - Gainsharing CMP
    - Certain applications of the CMP for inducements to beneficiaries

Fraud and Abuse

- Waiver Mechanics
  - Generally apply uniformly to ACOs, ACO participants, and ACO providers/suppliers
  - Intended to be self-implementing
    - Parties do not apply for individualized determinations of the waiver authority
  - No intent to codify waivers in CFR
    - Text of waivers will be available on CMS and OIG websites and is included in the Rule

Fraud and Abuse

- Waiver Mechanics
  - Require contemporaneous documentation and audit trail that is maintained for at least 10 years
  - No requirement for written and signed agreement
  - No requirement that arrangements are fair market value or assessed to be commercially reasonable

Fraud and Abuse

- Waivers
  - ACO pre-participation (new)
  - ACO participation (new)
  - Shared savings distributions (modified)
  - Compliance with the physician self-referral law (modified)
  - Patient incentive waiver for beneficiary inducements to encourage preventive care and compliance with treatment regimens (new)

Fraud and Abuse

- ACO pre-participation waiver
  - Covers start-up arrangements that pre-date an ACO's participation in the MSSP
  - Does not include manufacturers, distributors, HHA or DME companies

Fraud and Abuse

- ACO pre-participation waiver
  - Good faith intent to develop ACO to participate in MSSP within 1 year
  - Diligent steps to develop ACO that would be eligible for MSSP
  - “Bona fide” determination that the arrangement is reasonably related to the purposes of the MSSP
  - Contemporaneous documentation
  - Public disclosure of arrangement description

Fraud and Abuse

- ACO participation waiver
  - Blanket waiver
    - Covers all aspects of an arrangement between an ACO, one or more ACO participants or ACO providers/suppliers or any combination

Fraud and Abuse

- ACO participation waiver
  - ACO has entered into participation agreement under MSSP and is in good standing
  - ACO meets governance, leadership and management requirements of MSSP
  - “Bona fide” determination that arrangement is reasonably related to purposes of MSSP
  - Contemporaneous documentation of arrangement and authorization by governing body
  - Public disclosure of arrangement description

Fraud and Abuse

- Shared savings distribution waiver
  - ACO has entered into participation agreement under MSSP and is in good standing
  - Shared savings are earned by ACO pursuant to MSSP
  - Shared savings earned during participation agreement
  - Distributions must be shared with ACO participants or used for activities reasonably related to purposes of MSSP
  - For Gainsharing CMP, distribution cannot be related knowingly by a hospital to induce a physician to reduce or limit medically necessary services

Fraud and Abuse

- Compliance with physician self-referral law waiver
  - Arrangements that implicate Stark law and comply with a Stark exception shielded from AKS and Gainsharing CMP
  - ACO has a participation agreement with CMS under MSSP and is in good standing
  - Financial relationship is reasonably related to the purposes of MSSP
  - Financial relationship fully complies with a Stark exception

Fraud and Abuse

- Patient incentive waiver
  - Applies to beneficiary inducement CMP and AKS for certain items and services provided by ACO, ACO participants or ACO providers/suppliers to beneficiaries for free or at below fair market value
  - Waiver applies to all beneficiaries, not just those assigned to the ACO

Fraud and Abuse

- Patient incentive waiver
  - ACO has a participation agreement with CMS under MSSP and is in good standing
  - Reasonable connection between items or services and medical care provided to the beneficiary
  - Items or services are in-kind - does not include waivers of co-payments or deductibles

Fraud and Abuse

- Patient incentive waiver
  - Preventive care items or services or advance one or more of the following clinical goals
    - Adherence to a treatment regime
    - Adherence to a drug regime
    - Adherence to a follow-up care plan
    - Management of a chronic disease or condition.

Antitrust—Background

- Final ACO Antitrust Statement at 76 Fed. Reg. 67,026 (Oct. 28, 2011)
- Proposed ACO Antitrust Statement issued March 31, 2011
- 127 public comments filed with agencies; numerous criticisms and recommendations
- Biggest concern: The mandatory antitrust review requirement
- Final Statement reflects many of the concerns expressed in the public comments, but not all

Antitrust—Why Any Antitrust Statement?

- Many ACOs will result from “collaborations”
- Collaborations will result in price-fixing agreements
  - ACOs will likely include competitors
  - ACO actions will result from “agreements”
  - ACOs will jointly negotiate prices
  - Joint negotiation of prices by competitors result in price-fixing agreements
  - Price-fixing agreements among competitors are normally per se unlawful

Antitrust—Why Any Antitrust Statement?

- Collaborations may aggregate market power
  - ACOs may obtain the ability to increase reimbursement to commercial health plans to supracompetitive levels
- ACOs need more antitrust certainty to encourage development

Antitrust—Provider-Controlled Network (PCN) Antitrust Analysis

- PCNs and ACOs are joint ventures
- In the jargon of *Antitrust Health Care Statement* 9, ACOs are "Multiprovider Networks"
- Are their joint negotiations of prices per se unlawful?
  - Integration, plus reasonable necessity for restraint
    - Financial and clinical integration
    - ACOs, in effect, are clinically integrated PCNs
  - Shared risk: Sufficient financial integration?

Antitrust—Provider-Controlled Network (PCN) Antitrust Analysis

- Applying the rule of reason
  - Too much market power?
    - Adequate health-plan provider alternatives?
- See Statements 8 and 9 of the *Antitrust Health Care Statements* and agency PCN advisory opinions and business review letters

Antitrust—What Issues Does the Final ACO Antitrust Statement Address?

1. PCNs to which the Statement applies

2. When the Rule of Reason applies to ACO joint-price negotiations

3. A Rule of Reason Antitrust Safety Zone

4. Rule of Reason guidance for ACOs outside the Safety Zone

5. An expedited voluntary antitrust review letter process

Antitrust: 1. Application of the Statement

- Applies only to "ACOs"
  - Must participate, or intend to participate, in the Medicare Shared Savings Program
- Applies only to ACOs formed through "collaborations"
  - Applies regardless of when the PCN was formed (different from the Proposed Antitrust Statement)
  - Does not apply to ACOs formed through mergers that constitute a single entity (Same as Proposed Statement)
    - But their formation through mergers is subject to § 7 of the Clayton Act and the federal agencies' *Horizontal Merger Guidelines*

Antitrust: 2. When Does the Rule of Reason Apply?

- If the ACO complies with the CMS eligibility requirements (Same as Proposed Statement)
  - Why? Sufficient indicia of clinical integration.
  - Requires:
    - Formal legal structure
    - Formal clinical and administrative processes
    - Processes promoting evidence-based medicine
    - Quality and cost reporting and monitoring
    - Coordinated care for patients
  - Safety Zone applies to ACO contracting with private insurers if the same structure and processes are used

Antitrust: 3. The Rule-of-Reason Safety Zone

- Safety zone applies if no ACO participant common-service market share exceeds 30%
  - Why 30%?
  - Basically, the same as under Proposed Antitrust Statement
  - Relevant product markets: Medicare Specialty Codes, Major Diagnostic Categories, Outpatient Categories
  - Relevant geographic markets: Primary Service Areas (PSAs)
    - Under Final Statement, zip codes need not be contiguous
  - Clarification of what providers constitute an "ACO Participant" and thus must have shares calculated
  - As to physicians, doesn't matter whether they're exclusive or non-exclusive to the ACO
  - *But:* Any hospitals and ASCs must be non-exclusive
    - True regardless of the number of other facilities in the market

Antitrust—The Rule-of-Reason Safety Zone

- Exceptions to the Safety-Zone 30% rule, where the Safety Zone still applies:
  - *Dominant Provider Exception*:
    - A participant with a share in its PSA exceeding 50%, where no other participant provides the same service in that PSA
    - Must participate on a non-exclusive basis
    - ACO can't require any health plan to contract exclusively with it or otherwise prevent health plans from contracting with other providers

Antitrust—The Rule-of-Reason Safety Zone

- Exceptions to the Safety-Zone 30% rule, where the Safety Zone still applies:
  - *Rural Exception:*
    - One physician or physician group per each "rural area," regardless of the 30% limitation, but only on a non-exclusive basis
    - Any rural-hospital participant must be non-exclusive (what about ASCs?)

Antitrust—The Rule-of-Reason Safety Zone

- Observations:
  - ACO doesn't have to do the market-share calculations if it doesn't care about the Safety Zone and is comfortable it doesn't have market power
  - Safety zone protection lasts only for the duration of ACO's agreement with CMS
  - Protection lost if any share, during the agreement, exceeds 30% unless the reason is growth in patients (e.g., adding new providers)
  - Applies, as a technical matter, only to "ACOs"; i.e., PCNs participating in the Shared Savings Program
  - Safety Zone applies except in "extraordinary circumstances." What might these include?

Antitrust: 4. Rule-of-Reason Guidance Outside the Safety Zone

- Issue is the ACO's market power
- No presumption of power just because ACO is outside the Safety Zone
- Very little guidance about the actual Rule of Reason analysis the agencies will apply
- But see:
  - *Health Care Statements* 8 and 9
  - Agency *Antitrust Guidelines for Collaborations Among Competitors*
  - FTC clinical-integration staff advisory opinions
  - Traditional joint-venture decisions
  - Traditional Rule-of-Reason decisions

Antitrust—Rule-of-Reason Guidance Outside the Safety Zone

- Ultimate question:
  - If the ACO attempted to raise prices anticompetitively, would health plans have sufficient alternative providers so they could circumvent the price increase? Or is the ACO a "must have" for health plans?
- Some factors to consider:
  - Actual relevant product and geographic markets
  - Participant market shares
  - ACO participation percentages
  - Degree of participant exclusivity
  - Whether participants are "cream of the crop" providers
  - Particular services in which shares are large
  - Need for inclusion of all the participants
  - Efficiencies

Antitrust—Rule-of-Reason Guidance Outside the Safety Zone

- Final Statement warns ACOs with large shares about engaging in certain conduct (some of which can actually be procompetitive):
  - Sharing of competitively sensitive information among participants
    - Warning applies to *all* ACOs, even those within the Safety Zone
      - Concern is participant price-fixing agreements and price stabilization in dealing with health plans outside the ACO
  - Prohibiting or disincentivizing health plans from steering patients to other providers
  - Conditioning the sale of the ACOs services on health plans' not purchasing services from non-participants, or on purchasing services from participants when those services are not part of the ACO's services
  - Contracting with participants on an exclusive basis
  - Restricting the ability of health plans to provide members with performance information

Antitrust: 5. The Expedited Voluntary Antitrust Review Letter Process

- The Proposed Statement *required* all ACOs with *any* participant PSA market share above 50% to obtain a positive antitrust review letter from one of the agencies
  - The most criticized aspect of the Proposed Statement
  - Under the Proposed Statement, absent a positive review letter, the ACO could not participate in the Shared Savings Program
  - This meant, in essence, that every ACO had to do the laborious, expensive, confusing, and time-consuming PSA market-share calculations
  - The Final ACO Statement removes the mandatory review requirement
    - No ACO must obtain a review letter, but may seek one voluntarily
    - Participation in the Shared-Savings Program is not conditioned on a positive antitrust review letter
  - The biggest change in the Final Statement
  - Removes a huge amount of work for both ACOs and the agencies
  - A huge, huge improvement

Antitrust—The Expedited Voluntary Antitrust Review Letter Process

- But “newly formed” ACOs *may* obtain an expedited voluntary antitrust review letter if they want more certainty
- “Newly formed ACO”—ACOs that as of 3/23/10 had not signed any contracts or jointly negotiated with commercial health plans
- Final Statement lists information that must be submitted, including the PSA of each participant, and PSA share calculations if the ACO has calculated them
- ACO invited to submit additional information “that it believes may be helpful to the agency”; Final Statement includes examples
- Agency may request additional information, but this does not extend the 90-day period; ACO may voluntarily extend the period
- Agency will respond within 90 days of receiving all listed information, stating whether the ACO is “not likely to raise competitive concerns,” “potentially raises competitive concerns,” or “likely raises competitive concerns”

Antitrust—The Expedited Voluntary Antitrust Review Letter Process

- Agency will apply *Health Care Statements* and *Collaboration Guidelines*
  - Really just a Rule-of-Reason analysis
- No explicit prohibition on participation in Shared Savings Program if the letter is negative (Different from the Proposed Statement)
- As a technical matter, a positive letter doesn't preclude either the agencies or private parties from suing the ACO for antitrust violations
- Will be interesting to see if many ACOs request a voluntary review letter, given the conclusive presumption that the Rule of Reason applies to joint negotiations

Antitrust—Final Observations and Questions

- To what extent, at least as a practical matter, will the Final Statement's standards apply to PCNs not participating in the Shared Savings Program?
- Deletion of the mandatory antitrust review process, to a large extent, guts the Antitrust Statement; on balance, the Final Statement is pretty innocuous
- Don't expect the agencies to be any less zealous in challenging anticompetitive PCNs, be they ACOs or not
- All else equal, it's probably wise to calculate ACO participant market shares, even though there is no requirement to do so.

Antitrust—Final Observations and Questions

- In light of the Final Statement, should the agencies reexamine *Health Care Statements* 8 and 9? Are they and the Final ACO Antitrust Statement consistent? Should they be?
- No discussion in the Proposed or Final Statement about exclusion of providers wishing to participate, a fertile area of private antitrust litigation
- Are ACOs just another health-care fad or here to stay?
- All in all, the antitrust laws should not be a deterrent to development of procompetitive ACOs

Quality

- Must meet the Quality Performance Standards to be eligible for shared savings program
- Must completely and accurately report data on all program measures
  - Possible sanctions or termination for failure to comply
  - Will require significant infrastructure and coordination
  - Freedom of choice issue

Quality

- Proposed Rule
  - 65 measures - 5 domains
- Final Rule
  - 33 measures - 4 domains
  - Patient/Caregiver Experience - **7 measures**
  - Care Coordination/Patient Safety - **6 measures**
  - Preventative Health - **8 measures**
  - At-Risk Populations - **12 measures**

Quality

- Quality measure data collection methods
  - Claims data
  - Group Practice Reporting Option data collection tool
  - Survey instruments

Quality

- **Year 1:** pay-for-reporting
  - Complete and accurate data reporting on all program measures
- **Year 2:** mix
  - 8 measures pay-for-reporting
  - 25 measures pay-for-performance
- **Year 3+:** pay-for-performance
  - Except: health status/functional status module from survey results

Quality

- Subsequent Years: pay-for-performance
  - Based on ACO's performance across quality measures as compared to established benchmarks
  - ACOs with better quality scores obtain higher shared savings payments

Quality

- Patient surveys
  - Consumer Assessment of Health Care Providers and Systems (CG-CAHPS)
  - CMS wants standardized surveys and results
  - It's on CMS for 2012 and 2013
  - 2013 – ACOs pay
  - Change provider behavior

Quality

- Physician Quality Reporting System
  - Eligible professionals may only participate in PQRS incentive as a group practice under their ACO participant TIN
  - ACO must submit quality data on GPRO quality measures

Privacy and Health Information Technology

- Three types of data sharing
  - Data reporting to CMS
  - Aggregated data from CMS
  - Data sharing among ACO Participants

Note: Quality closely tied to HIT

Privacy and Health Information Technology

- Aggregate data from CMS
  - Beginning of agreement and quarterly
  - No real time reporting
  - De-identified
  - Prospective beneficiary assignment
  - Minimum necessary certification

Privacy and Health Information Technology

- Beneficiary identifiable data
  - Opting out
  - Meaningful opportunity
  - Data Use Agreement
  - Notification:
    - Primary Care Office
    - Written
  - Minimum necessary certification

Privacy and Health Information Technology

- Data sharing among ACOs
  - Important skill
  - Those participating in ACO are not all a *covered entity*
  - May not use or disclose PHI in a manner a HIPAA covered entity could not use or disclose

Privacy and Health Information Technology

- So, do you need an EHR to have an ACO?
  - Now a quality standard with 4 points rather than 2
  - Counted under Care Coordination domain
  - Looking to physicians
  - CMS may reconsider requirement of certified EHR technology, once providers gain more experience

Notifications

- CMS focused on dialogue between provider and beneficiary about new delivery system
- Posting signs
  - Beneficiaries outside ACO see these signs
- Written notices
  - Preliminary perspective assignment makes this easier

Marketing

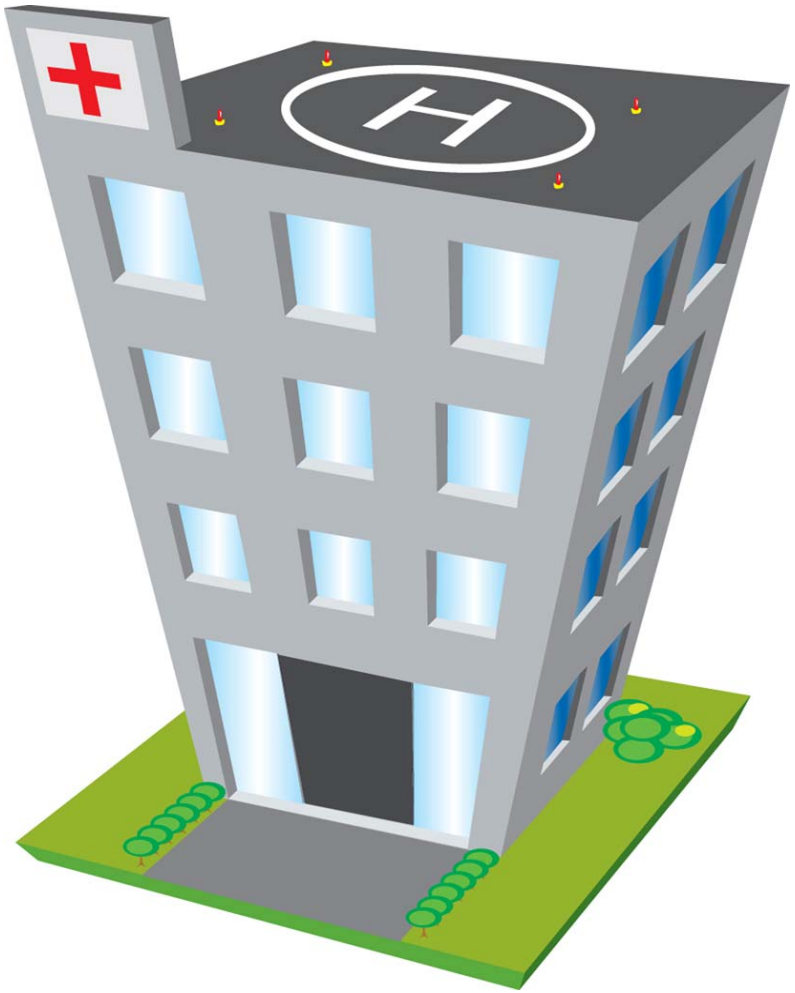
- Now includes social media (*i.e.*, Twitter or Facebook)
- Approval
  - Prior approval still needed
  - 5 days following submission if ACO certifies compliance with marketing requirements
  - CMS can disapprove at any time
- ACO can face sanctions and termination

Marketing

- Requirements – Must meet all:
  - Use template language developed by CMS, if available
  - Not be used in a discriminatory manner or for discriminatory purposes
  - Comply with beneficiary inducement rules
  - Not be material inaccurate or misleading

Tax Exemption
Hospitals and Other Healthcare Organizations

- **Control:** Hospitals don't need to control
  - IRS looked to CMS regulations and oversight
- **Private Inurement and Private Benefit:**
  - 5 factors
  - Clarification not all factors needed



CMS Innovation Center

- Charge
  - ACA: “Test innovative payment and service delivery models to reduce program expenditures, while preserving or enhancing the quality of care”
- Three aims
  - Better care for individuals
  - Better care for populations (e.g., certain diagnosis)
  - Lower growth of expenses
- $10 Billion in funding for FY 2011-2019

CMS Innovation Center

- Pioneer ACO Program
- Advanced Payment Initiative
- Bundled Payments
- Comprehensive Primary Care

Note: No double dipping (in certain cases)

Questions

Questions? Contact Us.

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