

The ACO Regulations Are Here: Are You Ready?



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Proposed Rule

- CMS “put on display” the ACO Notice of Proposed Rulemaking on March 31, 2011: <http://www.cms.gov/sharedsavingsprogram/>
- The ACO NPRM is scheduled to be officially published in the Federal Register on April 7, 2011.
- Deadline for comments is June 6, 2011.
- Other agencies – IRS, HHS/OIG and FTC/DoJ – have released notices of proposed rulemaking / policy statements as well
 - IRS: <http://www.irs.gov/pub/irs-drop/n-11-20.pdf>
 - HHS/OIG: <http://oig.hhs.gov/fraud/aco.asp>
 - FTC/DoJ: <http://www.ftc.gov/opp/aco/>

Proposed Rule, con't



- Comments regarding the HHS/OIG notice on fraud and abuse policy are due June 6, 2011
- Comments to the IRS notice regarding tax issues are due May 31, 2011
- Comments to the FTC/DoJ proposed antitrust policy statement are due May 31, 2011

Statutory Mandate

- Section 3022 of the Patient Protection and Affordable Care Act (“PPACA”) directs the Secretary to establish shared savings program no later than Jan. 1, 2012
- Purpose of program required by statute to “promote[] accountability for a patient population and coordinate[] services under parts A and B, and encourage[] investment in infrastructure and redesigned care processes for high quality and efficient service delivery.”

Statutory Mandate



- Under the program, groups of providers of services and suppliers are provided financial incentives to work together in an ACO where they manage and coordinate care for Medicare FFS beneficiaries
- ACOs that achieve lower costs and meet certain quality performance standards are eligible for shared savings payments and other incentives that CMS may establish

Roadmap

- Eligibility, Structure, and Governance (42 C.F.R. § 425.5)
- Assignment and Marketing (42 C.F.R. § 425.6)
- Data (42 C.F.R. § 425.19)
- Quality (42 C.F.R. §§ 425.8, 425.9, 425.10, and 425.17)
- Payment and Sharing (42 C.F.R. § 425.7)
- Compliance Obligations, Structures, Programs (42 C.F.R. § 425.5)
- Fraud and Abuse (Waiver Notice issued by CMS and HHS-OIG)
- Antitrust (Antitrust Policy Statement issued by FTC and DoJ)
- IRS Guidance to Tax Exempt Organizations
- SNR Denton Observations – Connecting the Dots
- Questions?

Structure and Formation

- Structure and Formation
 - Eligible Organizations
 - Legal Eligibility Conditions
 - Governance
 - Leadership and Management Structure
 - Distribution of Savings
 - Contractual Obligations to CMS and Programmatic Requirements

Structure and Formation: Eligible Organizations

- ACOs may be formed by the following organizations:
 - ACO professionals in group practice arrangements.
 - Networks of individual practices of ACO professionals.
 - Partnerships or joint venture arrangements between hospitals and ACO professionals.
 - Hospitals employing ACO professionals.
 - Providers or suppliers otherwise recognized under the Social Security Act.
 - CAHs that meet certain criteria.
- ACOs must have established a mechanism for shared governance to participate in the Shared Savings Program.
 - Existing ACOs do not have to create a new structure.
- ACOs are required to enter into a three-year contract with CMS.
- ACOs must have at least 5,000 beneficiaries and a commensurate number of physicians.

Structure and Formation: Legal Eligibility Conditions

- ACO must be recognized as a legal entity in the State in which it is established, and must have a TIN.
 - **Program Enrollment Not Required:** The ACO's legal entity does not need to be a participating Medicare entity.
- Must be capable of -
 - receiving and distributing shared savings;
 - repaying shared losses;
 - establishing, reporting, and ensuring ACO participant and ACO provider/supplier compliance with health care quality criteria, including quality performance standards; and
 - performing the other ACO functions identified in the statute.

Structure and Formation Governance

- Board Composition: Governing board must be representative of the organizations comprising the ACO.
 - Must include a Medicare beneficiary representative
- Possess broad responsibility for the ACO's administrative, fiduciary and clinical operations.
- ACO participants must have at least 75 percent control of the governing body.

Structure and Formation: Leadership and Management Structure

- **Operations Manager:** Operations must be managed by an executive, officer, manager, or general partner.
- **Medical Director:** Clinical management and oversight would be managed by a senior-level medical director who is a board-certified physician, licensed in the State in which the ACO operates, and physically present in that State.
- **Meaningful Commitment:** Participants must have a meaningful commitment to the ACO's clinical integration program to ensure its likely success.
- **Quality Assurance:** ACOs must have a physician-directed quality assurance and process improvement committee.
- **Clinical Guidelines:** ACOs must develop and implement evidence-based medical practice or clinical guidelines for delivering coordinated care.
- **Data Collection Infrastructure:** ACOs must have an infrastructure (i.e. information technology) that allows the ACO to collect and evaluate data and provide feedback across the organization, and report data to CMS.

Structure and Formation: Contractual Obligations to CMS and Requirements

- Three year agreement beginning January 1.
- ACO would be responsible for providing a copy of the agreement to its ACO participants and ACO providers/suppliers.
- The ACO contract with CMS may be changed:
 - Routine CMS “business operations”
 - Benefit Coverage Decisions
 - Additional Quality Measures
- ACO must provide in writing how it will implement changes.
- ACO must enter into Data Use Agreement.
- Two-Sided models also have surety bond, line of credit requirements.

Beneficiary Assignment

- FFS beneficiaries who receive primary care services from primary care physicians in ACOs are assigned to the ACO in which the beneficiary received a plurality of the services
 - Primary care physician must have a primary specialty designation of internal medicine, general practice, family practice, or geriatric medicine
 - Primary care services based on specified HCPCS codes
 - Plurality of services based on allowed charges
- Assignment is retrospective: Determined after close of performance year
- Assignment does not limit right of beneficiaries to choose non-ACO providers

Beneficiary Assignment, con't

- Given assignment methodology, primary care physician can only contract with one ACO (exclusive relationship); other ACO providers must not be required to be exclusive to a single ACO.
- At start of agreement period (and at end of each performance period), ACO upon request can (consistent with HIPAA) receive name, DOB, sex and HICN of beneficiaries who CMS determines would have been assigned to ACO in any of prior 3 available years, plus aggregated data (including de-identified utilization data).

Beneficiary Notices

- ACO providers must post signs in facilities and provide written notice to beneficiaries about their participation in the ACO.
 - CMS indicates that notices would be standardized
- ACO must also provide opt-out form to beneficiary prior to requesting claims data for the beneficiary from CMS; form must be provided as part of office visit with primary care physician.

Marketing to Beneficiaries

- All ACO marketing materials and communications such as mailings, telephone calls or community events regarding the ACO must be approved by CMS prior to use; subsequent changes must also be approved prior to use
- We expect marketing guidelines to closely resemble those applicable to Medicare Advantage plans
- CMS specifies certain communications that are not marketing materials and activities, including materials that do not include information about the ACO or providers in the ACO and materials that cover beneficiary specific billing and claims issues or other specific individual health related issues

Obtaining Medicare Parts A, B & D Data

- CMS will provide quarterly aggregated reports based on most recent 12 months of data for beneficiaries who potentially could be assigned to the ACO

- In addition, CMS will, upon ACO's request, share monthly beneficiary identifiable claims data on the ACO's potentially assigned beneficiary population
 - Sharing of monthly data is subject to limits, including:
 - beneficiary was seen in office of an ACO primary care physician during the performance year
 - beneficiary was informed about how the ACO intended to use the data and did not opt out of the data sharing
 - ACO executed a Data Use Agreement

Data Capture and Reporting Requirements

- ACOs will be required to report on certain quality measures
 - For performance year one, CMS is proposing 65 quality measures within the identified quality performance domains (patient/caregiver experience; care coordination; patient safety; preventive health; and at-risk population/frail elderly health)
 - Anticipation is that these quality measures will evolve over time
- Process
 - Data will be collected either through survey or a CMS-specified data collection tool
- Failure to report data may subject the ACO to termination from the Program

Quality Performance Metrics

- Year 1 - Proposes 65 measures for use in the reporting and calculation of the ACO Quality Performance Standard
- Quality performance standard for year 1 to be at the level of full and accurate measures reporting and all ACOs will receive full scores of either 50 or 60 for just full reporting in the first year
- Quality measures for the remaining two years of the 3-year agreement will be proposed in future rulemaking

Quality Performance Metrics, con't

- 65 Quality Measures divided between 5 domains
 - (1) Patient/Caregiver Experience;
 - (2) Care Coordination;
 - (3) Patient Safety;
 - (4) Preventive Health;
 - (5) At-Risk Population/Frail Elderly Health.

- Minimum attainment level of 30th percentile of Medicare FFS or MA rate

- See table on page 174 of advance copy of NPRM for list of proposed quality metrics.

Shared Savings: Payments



- Overview
 - Benchmarks
 - One-Sided Model
 - Two-Sided Model

Shared Savings: Benchmarks

- ACO providers will continue to be paid under the Medicare fee-for-service payment systems throughout participation in the ACO.
- To realize shared savings, ACOs must exceed a benchmark set by CMS.
- Three-year benchmark with increasing weight:
 - Benchmark is based on claims data from the previous three years for beneficiaries who *would have* been assigned to the ACO.
 - Weight of claims data increases as you approach 2012: claims data from 2008 is weighted 10%, claims data from 2009 is weighted 30% and claims data for 2010 is weighted 60%. The benchmark also includes annual updates to account for the increase in national Medicare fee for services expenditures.
- Benchmarks will include a 6-month claims runout.

Calculate Benchmarks

	2008	2009	2010
Average Spend	\$600.00	\$680.00	\$700.00
Trended Spend (assumes 4% growth)	648.96	707.20	700.00
Risk Index (BY3/BY1)	1.018	1.067	1.000
Adjusted Benchmarks	\$649.98	\$754.35	\$700.00
Risk Score	1.1	1.05	1.12

Calculate Benchmarks, con't

	2008	2009	2010
Benchmark	\$649.98	\$754.35	\$700.00
Weighting	.1	.3	.6
	65.00	226.30	420.00
Final 2010 Benchmark	\$711.30		

Calculate Benchmarks, con't

Final 2010 Benchmark	\$711.30
2011 Gross Increase	28.00
2012 Gross Increase	29.12
Final 2012 Benchmark	\$768.42

Shared Savings: One-Sided Model

- **One-Sided Model:** ACO shares only program savings for the first two years (but at a lower percentage than the two-sided model), and no program losses.
 - The third year, ACO must share both savings and losses (but can realize a greater percentage of savings).
- **Minimum Savings Rate (MSR):** Medicare computes an MSR based on the number of beneficiaries assigned to the ACO.
 - This rate ranges from 3.9% (for ACOs with 5,000-5,999 beneficiaries) to 2.0% (60,000+ beneficiaries).
 - Note: ACOs with fewer beneficiaries are more susceptible to large dips and spikes in experience.
 - Once MSR is reached, ACOs have “flipped the switch” and are eligible for shared savings.

Shared Savings: One-Sided Model

- **Shared Savings:** Under the one-sided model, an ACO that exceeds its MSR is eligible to share savings *net 2 percent of the benchmark*.
- The regulations include 4 exceptions exempting ACOs from the 2 percent net savings threshold (which allows for first-dollar savings):
 - (i) all ACO participants are physicians or physician groups; (ii) 75% or more of the ACO's assigned beneficiaries reside in counties outside an MSA; (iii) 50% or more of ACO's assigned beneficiaries were assigned on the basis of services received from Method II CAHs; and (iv) at least 50 percent of the assigned beneficiaries had at least one encounter with a participating rural health clinic (RHC) or federally qualified health center (FQHC).
- **To receive shared savings, an ACO must meet the requirements described above *and* demonstrate quality performance as described under §425.10.**
 - Shared savings are calculated on a sliding scale, by multiplying the savings rate and the quality score.

Shared Savings: One-Sided Model

- **Additional Increase to Shared Savings:** Under the one-sided model, an ACO's shared savings rate may be increased by 0.5% and up to 2.5% if the ACO includes a RHC or FQHC.
- **The amount of shared savings an ACO receives under the one-sided model may not exceed 7.5 percent of its benchmark.**
- **Under the One-Sided model, ACOs are eligible for shared savings of up to 50%.**
- In year three, One-Sided Models must move to the Two-Sided Model, and must share losses.

Shared Savings: Two-Sided Model

- **Under the Two-Sided Model**, ACOs can share up to 60% of the savings (compared for 50% under the One-Sided Model), but may also share in losses.
- **Minimum Savings Rate:** To qualify for shared savings, ACO's average per capita Medicare expenditures for the performance year must be *below its benchmark by at least 2%*
 - To qualify for savings, ACOs must meet minimum savings requirement
- **Minimum Loss Rate:** To share losses, an ACO's average per capita Medicare expenditures for the performance year must be at least *2% above its benchmark costs for the year.*

Shared Savings: Two-Sided Model

- **Qualification for Payment:** As with the One-Sided Model, ACOs must meet the minimum savings rate and also the minimum quality performance standards established under §425.10.
- **Increase in Shared Savings:** ACOs may increase their shared savings rate by up to 5.0 percentage points if the ACO includes a RHC or FQHC.
- **Payment Limit:** Under the Two-Sided Model, an ACO's shared savings is capped at 10% of its benchmark.

Shared Savings: Two-Sided Model

- **Shared Loss Rate:** With respect to the shared loss rate, plans that have losses that are high performance will share fewer losses than plans that are low quality and low performance.
- **Withholding:** In both models, gains are subject to a 25% withholding to help ensure repayment of losses to Medicare in later years.
- **Repayment Guarantee:** ACOs must obtain reinsurance, place funds in escrow, obtain surety bonds, or establish a line of credit that the Medicare program can draw upon to ensure repayment of any losses in advance of participating in the Shared Savings Program under the two-sided model.
- **Loss Caps:** The amount of shared losses may not exceed the following percentages over the yearly benchmark:
 - 5 percent in the first year
 - 7.5 percent in the second year
 - 10 percent in the third year

Compliance Burdens: Effective Compliance Plan

- Compliance obligations appear to closely track the Medicare Advantage requirements
- ACOs will be required to have an “effective” compliance plan
 - ACO may use or build on its own existing compliance plan, or the compliance plan of one of its ACO participants, but the ACO maintains ultimate responsibility for compliance with all terms and conditions of its agreement with CMS
- Specific requirements
 - In writing
 - Include policies and procedures

Compliance Burdens: Effective Compliance Plan, cont'd

– Include the following elements:

- A designated compliance officer (or individual) who is not legal counsel to the ACO and who reports directly to the ACO's governing body
- Mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance
- A method for employees or contractors of the ACO or ACO providers/suppliers to report suspected problems
- Compliance training for the ACO, the ACO participants, and the ACO providers/suppliers
- A requirement to report suspected violations of law

Compliance Burdens: Downstream and Related Entities

- Contracts with downstream and related entities
 - All contracts or arrangements between or among the ACO, its participants and providers/suppliers, and other entities furnishing services related to ACO activities must require compliance with the obligations under ACO-CMS agreement, including document retention requirements
 - CMS will monitor for the existence of, and adherence to, these requirements
 - Subject to audit by HHS-OIG

Compliance Burdens: Other

- Excluded providers
- HIPAA
 - Privacy and data security
- Document retention requirements
 - ACO records (*e.g.*, books, contracts, and other evidence, such as data related to Medicare utilization and costs, quality performance measures, shared savings distributions) must be retained for 10 years from the end of the agreement period
- Enforcement Actions
 - CMS may impose a wide range of enforcement actions, including termination, for failure to comply with these requirements

Fraud & Abuse Overview

■ Basic Concern

–ACO implementation will implicate and/or violate:

- health care program anti-kickback law (“AKL”),
- physician self-referral law (“Stark”), and/or
- services reduction civil monetary penalty law (“CMP”)

■ Congressional Response

–HHS may waive fraud and abuse laws as necessary to carry out the Medicare Shared Savings Program (“MSSP”)

Fraud & Abuse

Proposed Waivers - General

■ Overarching Objective

–Ensure F&A laws “do not unduly impede development of beneficial ACOs, while also ensuring that ACO arrangements are not misused for fraudulent or abusive purposes that harm patients or Federal . . . programs.”

■ Application

–Waivers to be applied “uniformly to all qualified ACOs, ACO participants and ACO providers/suppliers participating in” the MSSP.

- “Waiver” = advisory opinion?
- “Waiver” = exception/safe harbor?

Fraud & Abuse Waiver Requirements - General

- In order to qualify for any of the waivers (Stark, AKL or CMP):
 - ACO must have entered into an agreement with CMS to participate in the MSSP; and
 - Parties must comply with agreement and governing statutory and regulatory authorities, including, “without limitation, all transparency, reporting, and monitoring requirements”.
 - Potential Issue: is waiver protection lost even for technical, isolated, unrelated compliance failures?

Fraud & Abuse Waiver Requirements - Stark

- Only applies to “distributions of shared savings received by an ACO from CMS” under the MSSP.
 - Potential Issues:
 - Does not cover ACO ownership interests
 - Does not cover compensation arrangements that do not fall into the “shared savings distribution” category (e.g., administrative, consulting, etc.).

Fraud & Abuse Waiver Requirements - Stark

- Assuming threshold requirement met, applies if distributions are either:
 - “to or among ACO participants, ACO providers/suppliers, and individuals and entities that were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO,” or
 - “for activities necessary for and directly related to the ACO’s participation in and operations under the [MSSP].”
 - Potential Issue: “necessary” and “directly related to” are (highly) subjective.

Fraud & Abuse

Waiver Requirements – Anti-Kickback Law

- Waiver available under two scenarios.
- First, “distributions of shared savings”
 - “to or among ACO participants, ACO providers/ suppliers, and individuals and entities that were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO,” or
 - “for activities necessary for and directly related to the ACO’s participation in and operations under the [MSSP].”
 - Identical to Stark waiver requirements.
 - Same issues, questions.

Fraud & Abuse Waiver Requirements - Anti-Kickback Law

- Second, “[a]ny financial relationship between or among the ACO, ACO participants, and ACO providers/suppliers necessary for and directly related to the ACO’s participation in and operations under the [MSSP] that implicates the [Stark Law] and fully complies with [a Stark Law] exception.”
 - So: the remuneration (1) may or may not take the form of shared savings distributions, (2) must be between a physician and a DHS entity, and (3) must qualify for protection under an existing Stark Law exception
 - If so, AKL “waiver”

Fraud & Abuse

Waiver Requirements – Civil Monetary Penalty

- Waiver available under two scenarios.
- First, “distributions of shared savings” where “the distributions are made from a hospital to a physician,” provided that:
 - the “payments are not made knowingly to induce the physician to reduce or limit *medically necessary* items or services,” and
 - the hospital and physician “are ACO participants or ACO providers/suppliers, or were ACO participants or ACO providers/ suppliers during the year in which the shared savings were earned by the ACO.”

Fraud & Abuse

Waiver Requirements - Civil Monetary Penalty

- Second, “[a]ny financial relationship between or among the ACO, ACO participants, and ACO providers/suppliers necessary for and directly related to the ACO’s participation in and operations under the [MSSP] that implicates the [Stark Law] and fully complies with [a Stark Law] exception.”
 - Same as AKL waiver.

Fraud & Abuse

Proposed Rule - Comments Requested

- Arrangements related to establishing ACO
- Arrangements related to operation of ACO
- Arrangements with “outside” individuals/entities
- Distribution of shared savings from private payors
- Other financial arrangements requiring protection
- Duration of waivers
- Additional safeguards
- Proposed waivers
- One-sided v. two-sided risk issue
- Existing EHR exceptions
- Beneficiary inducements

Fraud & Abuse Take Aways

- Positive First Step

- Broad protection as it relates to downstream distributions of shared savings
- Help where it's needed most: Stark and CMP
- Good CMP fix (“medically necessary”)

- Work to Be Done

- Process: up-front (AO) or floating (safe harbor)
- Commercial payor issues
- Stark and financial arrangements not involving shared savings distributions

Antitrust Issues

- **ACOs will have some or all of these elements:**
 - Collaborations among competitors or otherwise independent providers
 - Conduct limiting competition such as exclusive dealing or preferred providers
- **Traditional clinical integration and financial analyses**
 - If no or insufficient clinical or financial integration, or both, then likely price fixing
- **From an antitrust perspective, “ACO” is just a new name for typical joint ventures or contracts among independent providers**
 - Antitrust analysis is the same
 - Risks and penalties are the same

Antitrust Issues, cont'd

■ So What's New?

- No new rules if ACO's market share is less than 30 percent of each common service
 - Rural exception raises 30 percent
- No new rules if an ACO's market share is between 30 and 50 percent; however, ACO may request a voluntary antitrust review
- ACOs with a market share of over 50 percent in any common service must receive a letter from the antitrust agencies to allow participation in the Shared Savings Program

Antitrust Issues, cont'd

■ Why?

- Avoid creation of ACOs with market power
- Even though Medicare prices are fixed and no price competition exists, competition will exist on quality of care, innovations to improve care, and treatment options choices
- ACOs with market power also might:
 - Raise commercial prices
 - Cause access to care issues
 - Limit health care competition

IRS Guidance for Tax Exempt Organizations

- In general, IRS expects that tax exempt entities participating in ACOs will not be treated as receiving prohibited inurement or private benefit for tax purposes if the terms of the ACO are structured per the IRS guidance
- IRS also expects that tax exempt entities would not be subject to unrelated business income tax
- IRS is asking for comments regarding tax consequences for tax exempt entities that use the ACO for other purposes (such as negotiating with private payers)
- Tax exempt entities should review guidance carefully and consider implications and possible comments

Connecting the Dots

■ Payment Issues

- Cap on savings to be shared; there is not an unlimited “upside.”
- ACOs must hit quality measures to receive shared saving.
 - And, measures are expected to change and expand in years 2-3 of the program
- Timing / lag in actual receipt of shared savings payments
- Holdback of 25% of shared savings by CMS

■ Eligibility Issues

- 50% of ACO physicians must meet HITECH EHR “meaningful use” requirements
- Likely state licensure issues regarding risk bearing entity obligations
- Beneficiary involvement governance

Connecting the Dots, con't

■ Costs

- ACOs subject to comprehensive CMS oversight similar to Medicare Advantage
 - Compliance program and structure
 - Marketing materials
 - Monitoring by CMS
 - Audits
- Cash flow / upfront investment of time, money and resources
 - Proposed rule estimates \$1.75M needed for startup and first year costs

Connecting the Dots, con't

■ Other Considerations

- Requirements to monitor delegated and downstream entities
- Restricted ability to challenge CMS
- Beneficiary opt-out
- Public reporting of financial data and performance
- 3 year contract “lock in” subject to changing rules
 - ACO could terminate, but faces loss of investment and inability to participate in shared savings program for remainder of contract period

■ What We Don't Know

- How this program will intersect with CMMI models and pilots

Questions?



- Questions for the panel?

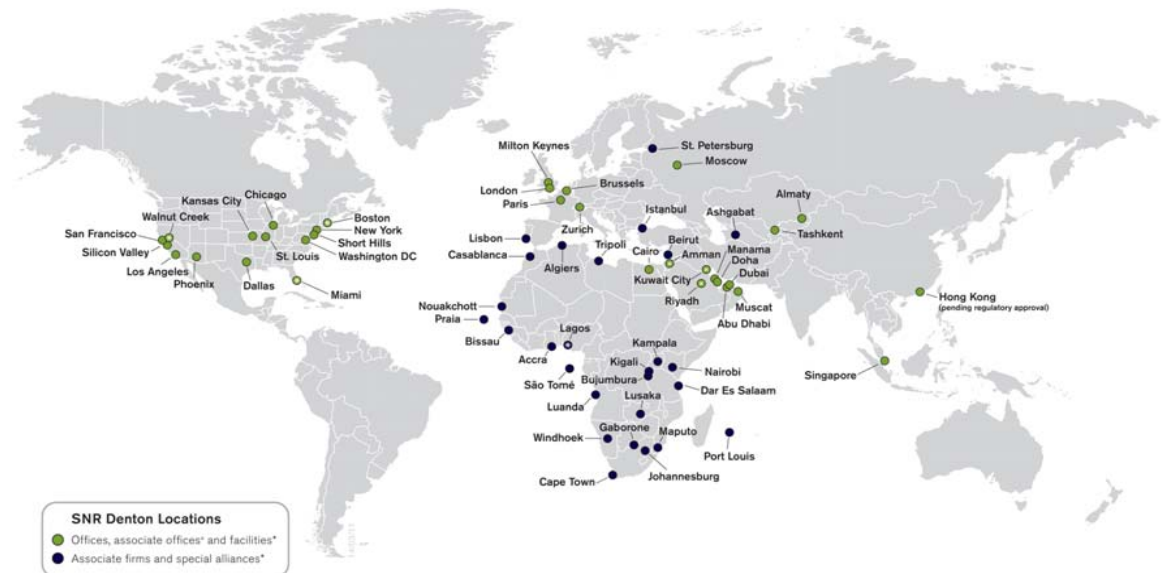
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