PROPOSED ACO REGULATIONS

An Accountable Care Organization (ACO) is an organization comprised of Medicare-enrolled providers and suppliers that agrees to share savings and losses with the Medicare program for beneficiaries allocated to it in proportion to its scores on quality performance standards (the "Shared Savings Program"). ACOs must demonstrate certain organizational and operational criteria, both in a CMS application and on an ongoing basis, in order to participate in the Shared Savings Program (including an ability to repay Medicare its share of any losses incurred). The final ACO Regulations should be issued by the end of 2011. The Shared Savings Program is scheduled to commence January 1, 2012.

I. Eligibility for Formation and Participation

Only certain Medicare enrolled providers and suppliers may form an ACO. The following, separately or in combination, may establish an ACO to participate in the Shared Savings Program.

- ACO professionals in group practice arrangements;
- Networks of individual practices of ACO professionals;
- Partnerships or joint venture arrangements between acute care hospitals paid under the hospital inpatient prospective payment system (IPPS) and ACO professionals;
- Acute care hospitals paid under IPPS employing ACO professionals; and
- Critical Access Hospitals (CAHs) that submit bills for outpatient services for both the facility and professional services ("Method II") can establish an ACO.

ACO professionals include: physicians, physician assistants, nurse practitioners and clinical nurse specialists.

Other Medicare enrolled entities/providers/suppliers may be ACO participants. Additional Medicare enrolled entities, such as FQHC's and RHC's, and other Medicare enrolled providers and suppliers may not form their own ACOs, but can participate in the Shared Saving Program by joining, as an ACO participant, an ACO containing one or more of the organizations that are eligible to establish an ACO.

II. Legal Structure

Organized under applicable State Law. ACO's must be an organization that is recognized to conduct its business under applicable State Law and is capable of: receiving and distributing should savings; repaying shared losses; establishing, and reporting and ensuring ACO participants and ACO provider/supplier compliance with program requirements; and performing other ACO functions. HHS is requesting comments on whether it should require ACO's participating in the Shared Savings Program to be formed as a distinct legal entity on whether an existing entity could be permitted to participate in the Shared Savings Program as an ACO, including entities that have similar arrangements with other payors.

Possessing a TIN; not required to be enrolled in Medicare. While each ACO participant must be enrolled in Medicare; the ACO itself is not required to be enrolled.

III. Governance

Governing body must have authority to execute statutory functions of ACO. An ACO must establish and maintain a governing body with adequate authority to execute the statutory functions of

the ACO, including but not limited to, the definition of processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care.

Governing body must be comprised of ACO participants and at least one Medicare beneficiary. The governing body must be comprised of ACO participants, or their designated representatives, and a Medicare beneficiary representative(s) serviced by the ACO who does not have, or whose immediate family members do not have, a conflict of interest with the ACO. ACO participants must have at least 75 percent control of the ACO's governing body and each ACO participant must have proportionate control over governing body decision-making. The members of the governing body may serve in a similar or complementary manner for an existing participant in the ACO.

ACO participants must have proportionate control of the governing body decision making. CMS comments to not define what proportionate control means, other than to say that each ACO participant would have a voice in the decision making process.

Governing body may include a community stakeholder. ACO's that have a community stakeholder organization serving on their governing body would be deemed to have satisfied the ACO application criteria for describing how they will partner with community stakeholders.

IV. Leadership and Management Structure

Governing body must control appointment and removal of ACO's executive. The ACO's operations must be managed by an executive, officer, manager, or general partner, whose appointment and removal are under control of the organization's governing body.

Leadership team must have demonstrated ability to influence or direct clinical practice to improve efficiency processes and outcomes. The ACO executive's leadership team must have demonstrated the ability to influence or direct clinical practice to improve efficiency processes and outcomes.

On-site, senior-level medical director to provide clinical management oversight. Clinical management and oversight must be managed by a senior-level medical director who is physically present on a regular basis in an established ACO location, and who is a board-certified physician, licensed in the State in which the ACO operates.

ACO participants and providers/suppliers must have meaningful commitment to clinical integration program. ACO participants and ACO providers/suppliers must have a meaningful commitment to the ACO's clinical integration program to ensure its likely success. Meaningful commitment may include, for example, a meaningful financial investment in the ACO, or a meaningful human investment (for example, time and effort) in the ongoing operations of the ACO such that the potential loss or recoupment of the investment is likely to motivate the participant and provider/supplier to make the clinical integration program succeed.

Physician-directed quality assurance and process improvement committee. A physician-directed quality assurance and process improvement committee must oversee an ongoing action-oriented quality assurance and improvement program. The quality assurance program must establish internal performance standards for quality of care and services, cost effectiveness, and process and outcome improvements, and hold ACO's providers/suppliers accountable for meeting the performance standards. The program must have processes and procedures in place to identify and correct poor compliance with such standards and to promote continuous quality improvement.

Hogan Marren, Ltd.
180 North Wacker Drive, Suite 600
Chicago, Illinois 60606

Telephone 312 946-1800
Fax 312 946-9818
www.hmltd.com

Evidence-based medical practice or clinical guidelines. The ACO must implement evidence-based medical practice or clinical guidelines and processes for delivering care consistent with the goals of better care for individuals, better health for populations, lower growth in expenditures. The guidelines and care delivery processes would cover diagnoses with significant potential for the ACO to achieve quality and cost improvements, taking into account the circumstances of the individual beneficiaries.

Compliance guidelines, performance evaluation, remedial action, and expulsion. ACO participants and providers/suppliers must agree to comply with compliance guidelines and processes and to be subject to performance evaluations and potential remedial actions, including their expulsion from the ACO. The ACO must have policies and procedures for expulsion of ACO participants and ACO providers/suppliers from the ACO.

Infrastructure to collect and evaluate data and provide feedback to the ACO providers/suppliers. The ACO must have an infrastructure, such as information technology, that enables the ACO to collect and evaluate data and provide feedback to the ACO providers/suppliers across the entire ACO, including providing information to influence care at the point of care.

V. Sufficient Primary Care Providers and Beneficiaries

ACO deemed to have sufficient primary care physicians and beneficiaries if the number of beneficiaries historically assigned to the ACO participants is 5,000 or more. CMS will deem an ACO to have a sufficient number of primary care ACO professionals to serve the number of Medicare beneficiaries assigned to it if the number of the beneficiaries historically assigned over the three year bench-marking period using the ACO participants' TINs exceeds the 5,000 threshold for each year. If an ACO's assigned population falls below 5,000 during the course of the agreement period, CMS will issue a warning and place the ACO on a corrective action plan. The ACO would remain eligible for Shared Savings for the performance year for which the warning was issued. If the ACO fails to meet the requirement of having more than 5,000 beneficiaries by the completion of the next performance year, the ACO's participation agreement would be terminated and the ACO would not be eligible for Shared Savings for that year. CMS also reserves the right to know the status of an ACO on an action plan and terminate the agreement on the basis that the ACO no longer meets the ACO eligibility requirements.

Beneficiaries assigned to an ACO based on utilization of primary care services. For each ACO, CMS will identify all primary care physicians who were an ACO participant during the performance year, determine the total allowed charges for primary care services received by each beneficiary who received services from a primary care physician in that ACO and assign a beneficiary to an ACO if the beneficiary has received a plurality of his or her primary care services, as determined by the sum of allowed charges for those services, from primary care physicians who are an ACO participant in that ACO. Note that the assignment of beneficiaries to ACO is retroactive.

VI. Application

Certification. The ACO executive must certify that the providers and suppliers forming the ACO have agreed to be accountable for and report to CMS on quality, cost and overall care of Medicare FFS beneficiaries assigned to the ACO.

Antitrust Review.

> ***PSA share less than 30 percent.*** Depending on ACO's share of its Primary Service Area ("PSA"), CMS may require or an ACO may chose to seek, an expedited antitrust review.

Hogan Marren, Ltd.
180 North Wacker Drive, Suite 600
Chicago, Illinois 60606

Telephone 312 946-1800
Fax 312 946-9818
www.hmltd.com

PSA share greater than 30 percent and less than or equal to 50 percent. Except for an ACO that qualifies for the Rural Exception articulated in the Antitrust Policy Statement or other controlling guidance, an ACO with a Primary Service Area (PSA) share greater than 30 percent and less than or equal to 50 percent for any common service area may: 1) request expedited Antitrust review from DOJ and the FTC; 2) submit as part of its application a letter from DOJ and FTC confirming that it has no present intent to challenge or recommend challenging the ACO; 3) begin to operate and abide by a list of conduct restrictions, reducing significantly the likelihood of antitrust concern such as avoiding contracting with certain ACO providers on an exclusive basis; or 4) begin to operate and remain subject to antitrust investigation if it presents competitive concerns.

PSA share greater than 50 percent for any common service. Except for an ACO that qualifies for the Rural Exception articulated in the Antitrust Policy Statement or other controlling guidance, an ACO with a Primary Service Area (PSA) share greater than 50 percent for any common service that two or more ACO participants provide to patients from the same PSA must: 1) request expedited Antitrust review from DOJ and the FTC and 2) submit as part of its application a letter from DOJ and FTC confirming that it has no present intent to challenge or recommend challenging the ACO.

Governing body. The ACO must provide evidence within its application that the governing body is a separate legal entity, i.e., organized under applicable state law and possessing a TIN.

Leadership and management structure. The ACO must submit supporting materials to demonstrate the ACO's management and leadership structure, including clinical and administrative systems that align with and support the goals of the Shared Savings Program and the aims of better care for individuals, better health for populations and lower growth in expenditures. Such supporting materials must include:

- ACO documents that describe the ACO participants' right and obligations in the ACO, including distribution of shared savings;
- Documents that describe the scope and scale of the quality assurance and clinical integration program;
- Supporting materials documenting the ACO's organization and management structure;
- Evidence that the medical director is a board-certified physician licensed in the state in which the ACO resides and that a principal CMS liaison is identified in the leadership structure;
- Evidence that representatives of the ACO participants comprise at least 75 percent of the governing body;
- Upon request, copies of all documents which effectuate in the ACO's formation and operation;
- A copy of the ACO's compliance plan;
- A description of how the ACO will partner with community stakeholders; and
- Written standards for beneficiary access and communication.

Distribution of savings. As part of its application, an ACO must describe how: 1) it plans to use shared savings payments, including the criteria it plans to employ for distributing shared savings among ACO participants; 2) the proposed plan will achieve the specific goals of the Shared Savings program and 3) the proposed plan will be used to achieve the general aims of better care for individuals, better health for populations and lower growth in expenditures.

Documentation of repayment mechanism. As part of its application, an ACO must submit for approval documentation of its repayment mechanism to ensure repayment of any losses to Medicare. This documentation must include details supporting the adequacy of the mechanism for repaying losses equal to at least one percent of the ACO's per capita expenditures for its assigned beneficiaries.

Hogan Marren, Ltd.
180 North Wacker Drive, Suite 600
Chicago, Illinois 60606

Telephone 312 946-1800
Fax 312 946-9818
www.hmltd.com

Documentation of plans to carry out statutory functions. In its application, an ACO must provide documentation of its plans to: 1) promote evidence-based medicine; 2) promote beneficiary engagement; 3) internally report quality and cost metrics; and 4) coordinate care.

VII. Marketing and Beneficiary Communication Guidelines

Notice of ACO participation to beneficiaries required. ACO participants must notify beneficiaries that their ACO providers/suppliers are participating in an ACO.

Marketing materials and beneficiary communications must be approved by CMS. All ACO marketing materials, communications and activities related to the ACO and its participation in the Shared Saving Program must be approved by CMS before use. Revisions to approved materials must also be approved by CMS before use.

Corrective action and termination. ACOs that fail to comply with these requirements may be placed under a corrective action plan or terminated at CMS's discretion.

VIII. Operational Requirements

Patient Centeredness. An ACO must demonstrate patient-centeredness by addressing all of the following:

- A beneficiary experience of care survey (using the Clinician and Group CAHPS survey, including an appropriate function status survey module) and how the ACO will use the results to improve care over time;
- Patient involvement in ACO governance;
- A process for evaluating health needs of the ACO's assigned population, including consideration of diversity in its patient populations, and a plan to address the needs of its population.
- Systems to identify and update high-risk individuals and processes to develop individualized care plans for targeted patient populations, including integration of community resources to address individual needs.
- A mechanism for the coordination of care.
- A process for communicating clinical knowledge/evidence-based medicine to beneficiaries in a way that is understandable to them.
- A process for beneficiary engagement and shared decision-making that takes into account the beneficiaries' unique needs, preferences, values and priorities.
- Written standards for beneficiary access and communication, and a process in for beneficiaries to access their medical record.
- Internal processes for measuring clinical or service performance by physicians across the practices, and using these results to improve care and service over time.

Compliance Plan. The ACO must have a compliance plan that addresses how the ACO will comply with the applicable legal requirements. The compliance plan must include:

- A designated compliance officer who is not legal counsel to the ACO and who has the ability to report directly to the ACO's governing body;
- Mechanisms for identifying and addressing compliance problems related to the ACO's operation or performance; and
- A method for employees or contractors of the ACO, ACO participants , and ACO provider/suppliers to report suspected problems related to the ACO;

Hogan Marren, Ltd.
180 North Wacker Drive, Suite 600
Chicago, Illinois 60606

Telephone 312 946-1800
Fax 312 946-9818
www.hmltd.com

- Compliance training for the ACO, the ACO participants and the ACO providers/suppliers; and
- A requirement to report violations of law to an appropriate law enforcement agency.

Conflict of Interest Policy. The ACO must have a Conflict of Interest Policy that applies to members of the governing body and requires disclosure of relevant financial interests. The policy must also include a procedure to determine if a conflict of interest exists, and set forth a process to address any conflicts that arise and remedial action for members of the governing body that fail to comply with the Policy.

Adequacy of ACO's repayment mechanism. An ACO must demonstrate to CMS the adequacy of its repayment mechanism to ensure repayment of any losses to Medicare prior to the start of each performance year in which it takes risk.

Signage and written notice requirements. ACO participants must post signs in each of their facilities and provide written notification for beneficiaries about their participation in the Shared Savings Program.

PQRS reporting. ACOs, on behalf of their eligible professionals, must submit measures required under the Physician Quality Reporting System (PQRS).

EHR meaningful use requirement for primary care physicians. At least 50 percent of an ACO's primary care physicians must be meaningful Electronic Health Record (EHR) users by the start of the second performance year in order to continue participating in the Shared Savings Program.

IX. Shared Savings Participation Agreement

Three year term starting January 1. The ACO Agreement must be for a term of three years, starting on the next January 1 following approval of the application, or such other date specified in the agreement.

Performance period of 12 months starting on January 1. The ACO's annual performance period under the ACO Agreement must be the 12-month period beginning on January 1 of each year during the term of the agreement.

May elect one of two tracks during initial term. During the term of its initial ACO Agreement, an ACO may elect to operate under one of two tracks. Under Track 1, the ACO operates under a one-sided model (sharing only savings) for two years and under the two-sided model (share losses, as well as savings) for the third year. Under Track 2, the ACO operates under the two-sided model, sharing in both savings and losses, for three years. For subsequent ACO Agreement periods, an ACO may only operate under the two-sided model.

Shared savings subject to 25 percent withhold. Under both Track 1 and Track 2, an ACO's shared savings will be subject to 25 percent withholding. The withhold will be applied toward repayment of an ACO's losses, if any. If the ACO completes the term of the ACO Agreement, CMS will refund any portion of the withheld savings not needed to offset losses. The withheld savings are forfeited if the ACO Agreement is terminated for any reason before the three-year term is completed.

Must establish repayment mechanism when under two-sided model. In addition to the shared savings withhold, ACOs under the two-sided model must obtain reinsurance, place funds in escrow, obtain surety bonds, establish a line of credit as evidenced by a letter of credit that the Medicare program can draw upon, or establish another repayment mechanism to ensure repayment of losses to Medicare in advance of performance year.

Hogan Marren, Ltd.
180 North Wacker Drive, Suite 600
Chicago, Illinois 60606

Telephone 312 946-1800
Fax 312 946-9818
www.hmltd.com

Subject to changes in statute or regulation, with few exceptions, and may have to supplement ACO application. During the term of the ACO Agreement, ACOs will be subject to all statutory changes and all changes in regulations, which can affect the requirements for the Shared Savings Program with the exception of the following program areas: 1) eligibility requirements concerning structure and governance of ACOs; 2) calculation of sharing rate and 3) beneficiary assignment. In those instances where changes in law or regulation require, or otherwise cause an ACO to change its processes in a manner that affects the design of its care processes and delivery of care, or changes to the quality of care, the ACO will be required to submit to CMS for review and approval, a supplement to its original application detailing how it will address key changes in processes resulting from these modifications. Failure to effectuate changes needed to adhere to the regulatory modifications would result in a corrective action plan and, ultimately, termination.

Prohibited from adding participants. During the term of the ACO Agreement, an ACO may remove, but not add, ACO participants (e.g., physician groups), but it may remove or add ACO providers/suppliers, e.g., an ACO participant that is a physician group may add or remove an individual physician from the group.

Certification of accountability for beneficiaries. As part of the ACO Agreement, the ACO must certify that the providers and suppliers forming the ACO have agreed to be accountable for and report to CMS on quality, cost and overall care of Medicare FFS beneficiaries assigned to the ACO.

Compliance with ACO regulations and agreement. All contracts or arrangements between or among the ACO, ACO participants, ACO providers/suppliers, and other entities furnishing services related to ACO activities must require compliance with the requirements of the ACO regulations, including those specified in the ACO Agreement and the ACO must provide a copy of the ACO Agreement to these individuals and entities.

Fraud and abuse compliance. The ACO must agree, and must require its ACO participants, ACO providers/suppliers, and contracted entities performing functions or services on behalf of the ACO to agree, or to comply with applicable provisions of: Federal criminal law; the False Claims Act; the Anti-Kickback Statute; the Civil Monetary Penalties Law and the Stark Physician Self-Referral Law.

Certifications of accuracy, completeness and truthfulness of information. The ACO must certify to the accuracy, completeness and truthfulness of information contained in its application, the ACO Agreement, submission of quality data and other information to CMS.

X. Data Sharing

Aggregate data. CMS will share aggregate data reports at the start of the agreement period based on historical data used to calculate benchmarks, as well as quarterly reports based on most recent 12 months of data from potentially assigned beneficiaries. Please note that because beneficiaries are assigned retroactively, the data received by the ACO during the year may not be based on the same beneficiaries which will be actually used in the calculation of savings and losses.

Beneficiary identifiable claims data. Subject to the beneficiary's opportunity to opt-out, CMS will, upon the ACO's request, provide monthly claims date for potentially assigned beneficiaries. Prior to receiving any beneficiary identifiable date, ACOs must enter into a Data Use Agreement with CMS.

Hogan Marren, Ltd.
180 North Wacker Drive, Suite 600
Chicago, Illinois 60606

Telephone 312 946-1800
Fax 312 946-9818
www.hmltd.com

XI. Quality Performance Score Calculation

CMS to designate quality performance standards. ACOs are considered to have met quality measures and applicable quality performance standard if they have reported quality measures and met applicable performance criteria for each of the three performance years.

For the first year, the quality performance standard is complete and accurate measures reporting. For the first performance period under the Shared Savings Program, CMS defines the quality performance standard at the level of complete and accurate reporting. For subsequent years, the quality performance standard will be based on a measures scale with a minimum attainment level. If an ACO signs up to participate on January 1, 2012, it will not know the subsequent quality performance standards until the next year.

ACOs must meet the quality performance thresholds for all measures to be eligible for shared savings. All measures within each of the five domains – patient/care giver experience; care coordination; patient safety; preventative health; and at-risk population/frail elderly health – must have a score above the minimum attainment level for the domain (30 percent) to be eligible for shared savings. All domains are weighted equally.

ACOs can be terminated for continued failure to meet quality performance standards or failure to report measures. If an ACO fails to meet minimum attainment level for one or more domains, the ACO will be given a warning and re-evaluated the following year. If an ACO continues to underperform the quality performance standards, it will be terminated. If ACO fails to report one or more measures after written request or exhibits a pattern of inaccurate or incomplete reporting or failure to make timely corrections following notice to re-submit, it may be terminated.

XII. Shared Savings Payment

Benchmark determined based on historical claims data and updated annually. CMS will retrospectively estimate and update an ACO's benchmark for an agreement period based on a 6-month claim run out for the ACO participants identified at the start of the ACO Agreement period. The benchmark is essentially the amount CMS would have expected to spend absent the ACO. CMS first computes the per capita expenditure for Part A and B claims of ACO participants based on beneficiaries who received the plurality of their primary care services from primary care physicians participating in the ACO in each of the prior three most recent available years. The benchmark is then adjusted for overall growth and beneficiary characteristics, and updated annually based on growth in national per capita expenditures for Part A and B services under the original Medicare FFS program.

IME and DSH payments are in the benchmark and expenditure calculation, value-based purchasing incentives and penalties are not. IME and DSH payments are included in the per capita costs included in the benchmark. Bonus payments for value-based purchasing initiatives, such as PQRS and EHR incentives and penalties, are excluded from the benchmark and actual expenditures. This could result in a perverse incentive for ACOs to avoid referrals to hospitals receiving IME or DSH payments in order to achieve greater savings.

To qualify for shared savings, ACO must exceed MSR and meet minimum quality performance standards. To qualify for shared savings, ACO's average per capita Medicare expenditures for the year must be below the benchmark by more than the ACO's minimum shared savings rate (MSR) and minimum quality performance standards must be met. The MSR for the one-sided model varies based on the number of Medicare beneficiaries while the MSR for the two-sided model is two percent.

Hogan Marren, Ltd.
180 North Wacker Drive, Suite 600
Chicago, Illinois 60606

Telephone 312 946-1800
Fax 312 946-9818
www.hmltd.com

Shared savings only for ACO on one-sided model. An ACO on the one-sided model, i.e., an ACO on Track 1 during the first two years of its ACO Agreement, that exceeds its MSR is eligible to share savings net two percent of its benchmark, unless it meets an exception from the two percent net savings adjustment. After adjusting for the two percent net savings threshold if required, an ACO that meets all the applicable requirements will receive a shared savings payment of up to 50 percent of the total savings, as determined by on the basis of its quality performance. The amount of shared savings an ACO receives may not exceed 7.5 percent of the ACO's benchmark. For example, if an ACO's per capita benchmark for assigned beneficiaries is $8,000 the maximum per capita shared savings payment could be $600 per beneficiary. The actual payment to the ACO will depend on the ACO's sharing rate, so that if an ACO had actual per capita costs of $7,000 and achieved a shared savings rate of 50 percent, based on its quality performance, the ACO would receive a payment of 50 percent of $600 less 2% or $12.00, or $294 of which $73.20 would be withheld of offset future losses. After two years on one-sided model, the ACO on Track 1 would shift to the two-sided model and be liable for an amount of loss up to five percent of its benchmark.

Shared savings and losses for three years for ACO on two-sided model. An ACO on the two-sided model, i.e., an ACO on Track 2 or an ACO on Track 1 during the third year of its ACO Agreement, that exceeds its MSR (two percent) is eligible to share savings on a first dollar basis. An ACO on the two-sided model will also be responsible for sharing any losses on a first dollar basis if its average per capita Medicare expenditures exceed the benchmark by at least two percent. An ACO that meets all the applicable requirements will receive a shared savings payment of up to 60 percent of the total savings, as determined by on the basis of its quality performance. The shared loss rate for an ACO required to share losses is determined based on the inverse of its shared savings rate (one minus the shared savings rate). The amount of shared savings an ACO on the two-sided model receives may not exceed 10 percent of the ACO's benchmark, and the amount of shared loss is limited to 5 percent of the benchmark in the first year of participation, 7.5 percent of the benchmark in the second year and 10 percent in the third year. For example, if an ACO's assigned average per capita benchmark for assigned beneficiaries is $8,000, the maximum per capital liability for losses could range from $400 to $800 for beneficiary, depending on which year the loss occurred. Actual liability will depend on the ACO's sharing rate, so that if the ACO had actual per capita costs of $8,800 in the third year and achieved a shared savings rate of 60 percent based on its quality performance, the ACO would be responsible for 40 percent of the $800 loss in year three, or $320.

Increased savings rate if ACO participants include RHC or FQHC. The shared savings rate for an ACO on the one-sided model may be increased by up to 2.5 percentage points if the ACO includes a RHC or FQHC during the performance year. The shared savings rate for an ACO on the two-sided model may be increased by up to 5.0 percentage points if the ACO includes an RHC or FQHC during the performance year.

XIII. ACO Reporting and Disclosure Obligations

TINs and NPIs. A participating ACO must maintain, update and annually report to CMS a list of the each ACO participant's TIN and each ACO provider's/supplier's NPI and/or TIN.

Public Disclosures. ACOs must make information on its accountability for quality, cost, and the overall care of it assigned population available to the public in a standardized format as determined by CMS. Such information will include:

- ACOs Name and location;
- Primary contact

Hogan Marren, Ltd.
180 North Wacker Drive, Suite 600
Chicago, Illinois 60606

Telephone 312 946-1800
Fax 312 946-9818
www.hmltd.com

- Organizational information;
- Shared savings information; and
- Quality performance standard scores.

Material Change to ACO participants or providers/suppliers and recalculated PSA. An ACO must notify CMS at least 30 days before any material change within the three-year ACO Agreement period of its ACO participants or ACO providers/suppliers and must resubmit recalculated Primary Service Area (PSA) shares for common services that two or more independent ACO participants provide to patients in the same PSA. If any revised PSA is calculated to be greater than 50 percent, the ACO will be subject to review or re-review by DOJ/FTC in order to remain eligible.

Letter from DOJ or FTC. If an ACO receives a letter from DOJ or FTC stating that either agency will likely challenge or recommend challenging the ACO, then the ACO must promptly inform CMS and it is ineligible to participate in the Shared Savings Program.

XIV. Termination of the ACO Agreement

CMS may terminate an ACO Agreement. CMS may terminate an ACO Agreement if the ACO, the ACO participants, the ACO providers/suppliers or contracted entities performing services or functions on behalf of the ACO:

- Avoid at risk beneficiaries.
- Fail to meet quality performance standards.
- Fail to completely and accurately report information or fail to make timely corrections to reported information.
- Are not in compliance with eligibility requirements or have fallen out of compliance with the requirements because the ACO has undergone material changes that affect the ACO's eligibility to participate in the Shared Savings Program.
- Are unable to effectuate any required regulatory changes during the agreement period after given the opportunity for a CAP.
- Are not in compliance with requirements to notify beneficiaries of ACO provider/ supplier participation in an ACO.
- Engage in material noncompliance, or demonstrate a pattern of noncompliance, with public reporting and other CMS reporting requirements.
- Fail to submit an approvable Corrective Action Plan (CAP), fail to implement an approved CAP, or fail to demonstrate improved performance after the implementation of a CAP.
- Violate the physician self-referral prohibition, civil monetary penalties (CMP) law, Anti-kickback statute, other antifraud and antitrust laws (or enter into a final judgment or other final resolution or antitrust charges by an Antitrust Agency), or any other applicable Medicare laws, rules, or regulations that are relevant to ACO operations.
- Submit to CMS false, inaccurate, or incomplete data and or information, including but not limited to, information provided in the Shared Savings Program application, quality data, financial data, and information regarding the distribution of shared savings.
- Use marketing materials or participate in activities or other beneficiary communications that are subject to review and approval, that have not been approved by CMS.
- Fail to maintain an assigned beneficiary population of at least 5,000 beneficiaries.
- Fail to offer beneficiaries the option to opt-out of sharing claims information.
- Limit or restrict internally compiled beneficiary summary of care or medical records from other providers/suppliers both within and outside of the Shared Savings Program to the extent permitted by law.

Hogan Marren, Ltd.
180 North Wacker Drive, Suite 600
Chicago, Illinois 60606

Telephone 312 946-1800
Fax 312 946-9818
www.hmltd.com

- Improperly use or disclose claims information received from CMS in violation of the HIPAA Privacy Rule, Medicare Part D Data Rule, Privacy Act, or the Data Use Agreement.
- Fail to demonstrate that the ACO had adequate resources in place to reply losses and to maintain those resources for the agreement period.

Reapplication after termination. An ACO that has been terminated from the Shared Savings Program may apply to participate in the Shared Savings Program again only after the end of the original three-year ACO Agreement period.

Forfeiture of mandatory shared savings withholding after termination. If an agreement is terminated for any reason before the three-year ACO Agreement period is completed, the ACO would forfeit its mandatory 25 percent withhold of shared savings.

Termination of an ACO Agreement by an ACO. An ACO must notify CMS, its ACO participants, and other organizations of its decision to terminate 60 days before the date of termination. The ACO participants must notify beneficiaries of the ACO's decision to terminate in a timely manner, and all termination notification materials must meet the ACO marketing guidelines.

XV. Shared Savings Payment Suspension

CMS must suspend shared savings payments if ACO avoiding at-risk beneficiaries. If an ACO has been placed under a CAP because the ACO, ACO participants, ACO provider/suppliers, or contracted entities performing services or functions on behalf of the ACO were found to have avoided at-risk beneficiaries, the ACO must not receive shared saving payments while it is under the CAP, regardless of the period of performance it is attributable to; and the ACO is not eligible to earn any shared savings for the performance period attributable for the time the AOC was it under the CAP.

* * *

For more information about the proposed ACO regulations, please contact your Hogan Marren attorney or any one of the following members of the firm:

	Telephone Number	Email Address
Thomas J. Babbo	312-946-1800	TJB@hmltd.com
Carol C. Hogan	312-946-1800	CCH@hmltd.com
John P. Marren	312-946-1800	JPM@hmltd.com
Sheila Sokolowski	312-946-1800	SS@hmltd.com

Hogan Marren, Ltd.
180 North Wacker Drive, Suite 600
Chicago, Illinois 60606

Telephone 312 946-1800
Fax 312 946-9818
www.hmltd.com