SUMMARY OF FINAL RULE AND GUIDANCE FOR THE SHARED SAVINGS PROGRAM: ACCOUNTABLE CARE ORGANIZATIONS

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On October 20, 2011, the Centers for Medicare and Medicaid Services (CMS) issued final regulations CMS-1345-F “Medicare Shared Savings Program: Accountable Care Organizations (ACOs)”. The Medicare Shared Savings Program was included in Section 3022 of the Affordable Care Act (ACA). Accountable Care Organizations provide incentives for health care providers to coordinate care for Medicare patients in the original Fee for Service program (FFS). The Shared Savings Program promotes accountability for a patient population, coordinates Part A and Part B services, and encourages investment in infrastructure and redesigned care processes for high quality and efficient services. Providers will be eligible for additional payments when services meet performance on quality standards and lower health care costs. The ACO program will begin January 1, 2012.

Participation in ACOs is voluntary for both providers and Medicare beneficiaries.

The final regulation estimates the shared savings program will result in $470 million net savings for CYs 2012-2015. These savings are lower than estimated in the proposed rule due to changes in payment in the final rule including allowing a one-sided model and first dollar sharing. The final rule also assumes that most ACOs will choose the one-sided (no risk) track. The regulatory impact analysis assumes one to five million Medicare beneficiaries will be assigned (compared to 1.5 to 4 million in the proposed rule) to 50 to 270 ACOs (compared to 75 to 150 in the proposed rule). The final rule assumes that ACOs will participate in markets at, below and above the average baseline per capita costs (compared to the assumption in the proposed rule that ACOs would be more likely to form in high-cost markets).The final rule estimates $0.58 million start-up costs per ACO and annual operating costs of $1.27 million. The total average start-up investment is estimated to range from $29 million to $157 million. These start-up costs when combined with operating costs are estimated to be $451 million for CYs 2012-2015. The bonuses are expected to be $1.31 billion (compared to $800 million in the proposed rule) which are calculated over an agreement period six to nine months longer than under the initial benchmark.

The CMS final rule on ACOs can be accessed online at
http://www.gormanhealthgroup.com/docs/ACOs%20-%20FINAL%20RULE%20Shared%20Savngs%20Program.pdf

This summary also addresses other policy and regulatory documents released with the final ACO regulations: the CMS Advanced Payment ACO model; the Office of Inspector General (IOG) Interim final regulation on waivers, the Federal Trade Commission (FTC) final policy statement on ACOs and the IRS Fact Sheet.

SIGNIFICANT CHANGES IN THE FINAL RULE

The final rule reduces the administrative burden and costs for participating ACOs compared to the provisions in the proposed rule. Some of the most significant changes include:

- Greater flexibility in eligibility to participate including participation of rural health centers (RHCs) and federally qualified health centers (FQHCs), and removing the requirement that 50 percent of primary care physicians meet meaningful use requirements;

- Multiple start dates in 2012 (April 1 and July 1) and longer agreement period for ACOs that start in 2012;
- More flexible governance and legal structure, e.g. alternative participant and beneficiary roles and participant contributions;
- Flexibility to add and subtract providers over the course of the agreement;
- Preliminary prospective assignment with a final reconciliation; opportunity to contact beneficiaries prior to point of service;
- Two-step assignment process that includes primary care services of other ACO professionals;
- No downside risk in Track 1
- Improvements in payments include: increased savings caps, first dollar savings after the minimum savings is reached, no 25 percent withholding, claim run-out reduced from six to three months, and adjustment to the benchmark and performance year expenditures;
- Risk adjustment updated for newly assigned beneficiaries;
- Option for interim payment with reconciliation if reporting CY 2012 quality measures;
- Simplified repayment of guarantee of one percent of benchmark and longer period to repay losses;
- Streamlined quality reporting process with measures reduced from 65 to 33 and domains reduced from 5 to 4;
- Phase-in of pay for performance reporting with pay for reporting in the first year
- CMS funding for patient experience-of-care survey in 2012 and 2013;
- Addition of two new “at-risk beneficiary” categories;
- Anti-trust review more flexible and not mandatory;
- Voluntarily termination of agreement when regulatory standards are established during the agreement period which impact the ability of the ACOs to continue in the program;
- ACO participants will no longer be required to notify beneficiaries when the participants no longer participate in the ACO program;
- File and use requirements for marketing materials.

The following is a summary of the major provisions in the ACO Shared Savings Program and the changes in the final rule. This is a summary and does not include all of the requirements.

ELIGIBILITY AND APPLICATION REQUIREMENTS FOR AN ACO

An ACO is a legal entity that has its own Taxpayer Identification Number (TIN), and is comprised of an eligible group of providers that are enrolled in the Medicare program and who also have TINs. ACO providers must commit to work together to coordinate care for Medicare FFS beneficiaries and to be accountable for quality, cost and care for assigned beneficiaries. The ACO must have established a mechanism for shared governance that provides all ACO participants with an appropriate proportional control over the ACO’s decision-making process.

The final rule adds two new groups of eligible providers – rural health centers (RHCs) and federally qualified health centers (FQHCs). Thus, the following types of groups of providers and suppliers are eligible to become ACOs:

- ACO professionals (i.e. hospitals and physicians) in group practice arrangements;

- Networks of individual practices of ACO professionals;

- Partnership or joint venture arrangements between hospitals and ACO professionals;
- Hospitals employing ACO professionals;
- Critical access hospitals (CAH) that bill through Method II under which a CAH bills for physician and other practitioner services;
- RHCs;
- FQHCs.

In allowing RHCs and FQHCs to independently sponsor an ACO, the final rule modifies the definition of an ACO to include legal entities under Federal and Tribal law. It also modifies the assignment and benchmarking processes to deal with their different payment and claims systems.

The legal entity can be a corporation, partnership, Limited Liability Company or foundation and must be responsible for the following:

- Receiving and distributing shared savings;
- Repaying shared losses or other monies owed to CMS;
- Establishing, reporting and ensuring provider compliance with health care quality criteria, including quality performance standards;
- Other ACO regulatory functions.

The regulations do not require existing legal entities to form a separate ACO entity if the existing entity does not add new organizations to the ACO and can meet the statutory eligibility requirements. This would apply, for instance, to an integrated health system that wanted to be designated an ACO based solely on services provided by its own physicians. An ACO formed by two or more otherwise independent ACO participants must be a legal entity separate from any of its ACO participants.

The ACO must certify that it is authorized to conduct business in each state in which it operates.

Each ACO must establish a governing body with authority to execute the functions of an ACO including the three-part aim. Seventy-five percent of the governing body must represent ACO providers and suppliers with a Medicare enrolled TIN. The governing body must include Medicare beneficiaries. The governing body must have a conflict of interest policy that includes disclosure of financial interests and a method for determining and remediating conflicts. However, the final rule allows the ACO to present alternative innovative ways that it will involve participants and Medicare beneficiaries in its governance as part of the application process.

The final rule clarifies that an existing legal entity is permitted to use its current governing body and that an ACO formed among independent participants must establish a separate and identifiable governing body. The final rule relaxes the requirement that each participant be on the governing body with proportionate control and instead requires that there be meaningful participation for ACO participants.

The ACO leadership and management structure must include clinical and administrative systems that support the goals of the shared savings program and the triple aim.

The operations must be directed by an executive under the control of the governing body and clinical management must be directed by a licensed and board certified physician. The final rule removes the requirement that the medical director be on site full-time and instead requires that clinical management oversight be a senior-level medical director who is one of the ACO's physicians who is physically present on a regular basis in an ACO location. The final rule also allows ACO applicants to describe alternative innovative leadership and management structures as part of the application.

The final rule relaxes the requirement that the ACO must have a physician-directed quality improvement committee and instead requires the ACO to describe in its application how it will establish and maintain an ongoing quality assurance and improvement program led by a qualified health care professional.

The preamble to the final rule supports the anti-trust agencies' encouragement of financially and clinically integrated ventures as consistent with the ACO required processes to promote evidence based medicine, report cost and quality metrics, promote patient engagement and coordinate care.

The final rule streamlines the document requirements submitted with the application to be consistent with the clinical and administrative requirements for ACOs. The documents must be sufficient to describe the ACO participants' rights and obligations to the ACO and documenting the ACO's organization and management structure. The application must certify that the ACO and participants are accountable for the quality, cost and overall care of assigned beneficiaries. The ACO application must document the scale and scope of quality assurance programs, clinical integration programs and internal performance standards. The ACO application must also document how it will use shared savings payments including criteria for distributing savings to participants and a description of how the program will meet the goals of the Shared Savings Program and the triple aim.

The ACO must describe in their application their plans (including partnerships with community stakeholders) to establish, evaluate and update the following required processes:

- Promote evidence-based medicine;
- Promote patient engagement, including compliance with patient experience-of-care survey and beneficiary representative requirements;
- Internally report quality and cost metrics;
- Coordinate care.

The ACO must also describe their plans to coordinate care which do not impede the beneficiary from seeking care from providers that are not part of the ACO.

The application must document how the ACO will promote patient-centeredness including:

- Conduct a CAHPS beneficiary experience survey and use results to improve care over time;

- Involve patients in ACO governance;
- Evaluate the health needs of the assigned population and develop plans to address the needs, including consideration of diversity;
- Use systems to identify high-risk individuals and develop individualized care plans, in particular for beneficiaries with multiple chronic conditions;
- Use mechanisms to coordinate care;
- Exchange summary of care information when patients transition to another provider or setting either in or outside of the ACO;
- Communicate understandable clinical knowledge and evidence-based medicine to beneficiaries and engage beneficiaries in shared decision making that takes into account the beneficiaries' unique needs, preferences, values and priorities;
- Develop written standards for beneficiary access and communication including access to medical records;
- Establish internal processes to measure clinical and service performance by physicians across practices and to improve over time.

The ACO must have a sufficient number of primary care ACO professionals to serve the FFS beneficiaries assigned to the ACO. The ACA requires that ACOs be accountable for at least 5,000 Medicare beneficiaries as assigned by CMS. If the assigned population falls below 5,000 there will be a corrective action plan and if the ACO does not achieve 5,000 by the end of the next year, their ACO agreement will be terminated and they will not be eligible for shared savings.

The final rule allows ACOs to add and subtract participants over the course of the agreement period with 30-day notice to CMS. The ACO must also notify CMS within 30 days of any significant change which would render the ACO to become unable to meet the eligibility or program requirements of the ACO program.

Each ACO will submit the TIN and associated National Provider Identifier (NPI) of each ACO participant and additional information on RHC and FQHC participants each year. The ACO and ACO participants must commit to a three-year agreement. Each ACO participant TIN upon which a beneficiary assignment is made must be exclusive to a single ACO. The preamble to the final rule clarifies that TINs will be used for beneficiary assignment when providers bill under the ACO TIN. Exclusivity will apply to ACO participants (primary care physicians, specialists, NPs, PAs, and CNs) whose primary care services are considered in the assignment process.

The ACO must have infrastructure (such as information technology) to collect and evaluate data and provide information to ACO participants across the entire ACO including at the point of care. The final rule no longer requires that 50 percent of primary care providers be meaningful users by the second performance year.

The ACO must sign a three-year agreement with CMS that attests to accountability and compliance of the ACO and its participants with federal laws and ACO requirements.

A performance year is generally each calendar year during the three-year agreement period.

The final rule changes the start date, length of the agreement and first performance period. ACOs can start April 1, 2012 or July 1, 2012 with an agreement period of three years and nine months or three years and six months, respectively. The first performance period will be 21 months and 18 months, respectively. Accountable Care Organizations can also start on

January 1 in 2013 or subsequent years. All other performance periods will be 12 months.

First Agreement Period -- Performance years, based on start date:

<table>
<tr><th></th><th>4/2012-12/2012 (9 months)</th><th>7/2012-12/2012 (6 months)</th><th>1/2013-12/2013</th><th>1/2014-12/2014</th><th>1/2015-12/2015</th></tr>
<tr><td>Start 4/1/2012</td><td colspan="3">1st Performance year (21 months)</td><td rowspan="3">2nd Performance year (12 months)</td><td rowspan="3">3rd Performance year (12 months)</td></tr>
<tr><td colspan="2">Start 7/1/2012</td><td colspan="2">1st Performance year (18 months)</td></tr>
<tr><td colspan="3">Start 1/1/2013</td><td>1st Performance year (12 months)</td></tr>
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PUBLIC REPORTING AND TRANSPARENCY

ACOs will be required to provide administrative information about the ACO to CMS and the public on both the quality and the financial performance of its operations. Administrative and organizational information includes:

- Name and location
- Primary contact
- Identification of ACO participants
- Identification of participants in joint ventures between ACO professionals and hospital
- Identification of the members of its governing body
- Identification of associated committees and committee leadership

Performance results include—

Shared savings and losses information:

1. Amount of any shared savings performance payment received by the ACO or shared losses owed to CMS.

2. Total proportion of shared savings invested in infrastructure, redesigned care processes and other resources required to support the three-part aim goals of better health for populations, better care for individuals and lower growth in expenditures, including the proportion distributed among ACO participants.

Patient surveys and claims-based measures:

> Quality measures will be reported as a group measure on Physician Compare. Some final changes will affect reporting under the Physician Quality Reporting System since a final regulation is expected in late 2011 in the CY 2012 Physician Fee Schedule.

CMS will develop standardized formats for all reported information. CMS will provide formats and additional instructions through sub-regulatory guidance to be developed.

BENEFICIARY ASSIGNMENT

In a major change from the proposed rule, under the final rule ACOs will receive a preliminary list of beneficiaries based on prospective assignment before each year begins. Also, CMS will consider primary care services provided by specialists and mid-level practitioners in making the assignments.

Beneficiaries will be assigned on the basis of the most recent twelve months' claim data. CMS will use a two-step process to make the assignment. In both steps, assignment will be determined by where a beneficiary receives the plurality of her or his primary care, as measured by allowable charges on Medicare Part A and Part B claims.

CMS has identified a range of HCPCS codes that they define as primary care services. Primary care codes are:

- 99201 through 99215;
- 99304 through 99340;
- 99341 through 99350;
- G0402 (the Welcome to Medicare visit);
- G0438 and G0439 (the annual wellness visits).

Additionally, the following revenue center codes used in Medicare billing by federally qualified health centers (FQHC) and rural health centers (RHC) will be considered to represent primary care services when billed under the National Provider Identifier (NPI) of a primary care physician. FQHCs and RHCs will submit lists of NPIs for their primary care physicians.

- 0521 Clinic visit by member to RHC/FQHC;
- 0522 Home visit by RHC/FQHC practitioner;
- 0524 Visit by RHC/FQHC practitioner to a member, in a covered Part A stay at the SNF;
- 0525 Visit by RHC/FQHC practitioner to a member in an SNF (not in a covered Part A stay) or NF or ICF MR or other residential facility;

In step one, CMS will determine an initial list of assigned beneficiaries by reviewing claims for primary care services submitted by physicians whose primary specialty, according to Medicare records, is a primary care specialty. Primary care specialties are general practice, internal medicine, family practice and geriatrics. Citing statutory provisions of the Affordable Care Act, CMS states that claims from mid-level practitioners (nurse practitioners, physicians' assistants, and clinical nurse specialists) cannot be considered. Beneficiaries will be assigned to an ACO based on a plurality rule. If the total Medicare allowable charges for a beneficiary for services received from an ACO's primary care physicians exceeds the beneficiary's primary care charges submitted by the primary care physicians of any other ACO, or are submitted by all primary care physicians who are not participating in an ACO, then the beneficiary is assigned to the ACO with the plurality of the charges. Assignment is based on total charges, rather than the number of visits, to reduce the likelihood of a tie between two ACO claiming the same patient. The calculation is based on the most recent twelve-month period for which CMS has data.

In step two, CMS will review claims for the remaining unassigned beneficiaries to identify beneficiaries whose twelve-month claim record includes at least one primary care service for any other ACO physician. From this group, CMS will exclude beneficiaries who have any claims from any primary care physicians, whether in or out of any ACO. CMS will then

assign beneficiaries to the ACO whose professionals have billed the greatest total allowable charges for primary care services. Note that in this second step, the assigned beneficiaries must have received at least one primary care service from a physician in the ACO to which they are assigned, but then all primary care services billed by all professionals (physicians, NP, PA, CNS) in the ACO are used to determine where the beneficiary is assigned.

To summarize:

- Step one:
  - Only primary care physicians' (PCP) claims are used;

- Step two:
  - Only for beneficiaries with no primary care physician claims
  - Must have at least one primary care service code from an ACO physicians (not a PCP);
  - Assignment based on plurality of allowable charges, both physician and mid-level;

In performing the second step, CMS does not make any differentiation among specialists. All primary care codes billed by participating physicians of any specialty are included. However, step two does exclude claims from primary care physicians, since those claims are considered in step one.

This assignment process is conducted prior to the ACO's initial contract period and then quarterly thereafter. The ACOs can use this list to provide beneficiaries with advance notification of their participation in the shared savings program and their intention to request beneficiary identifiable data. If the beneficiary does not opt out in 30 days, the ACO can request beneficiary identifiable data from CMS.

The quarterly lists will allow the ACO to track who is leaving and who is newly assigned, based on a rolling twelve-month claim history. The quarterly listings of preliminary prospective assignment of beneficiaries include limited identifiable beneficiary information (e.g. name, date of birth) and the opportunity to request monthly beneficiary identifiable claims data. The final rule clarifies that the minimum necessary data elements can include the identity of providers such as through a NPI or TIN and the POS code to facilitate coordination of care.

A final reconciliation is performed retrospectively after the end of each performance year, based on claims incurred during the performance year. Savings and losses will be based on the final retrospectively determined list of beneficiaries and actual beneficiary utilization. However, the prospective interim lists that CMS provides at the beginning of each year, quarterly throughout the year, will give the ACO a good notion of the beneficiaries for whom it is accountable.

ACCOUNTABLE CARE ORGANIZATION MODELS

CMS is retaining the two-track approach to calculating shared savings that was included in the proposed rule, with some significant changes. Also, the benchmark will be calculated and updated differently than was originally proposed, in an attempt to better adjust for risk.

BENCHMARK

The benchmark is the average per beneficiary cost that is used to set annual targets, for purposes of calculating whether an ACO is generating savings or losses. The benchmark will be calculated from three years of claims data, from the most recent calendar years for which complete claim data are available prior to the start of an ACO's agreement period.

The claims will be for beneficiaries who would have been assigned to the ACO, had it been in operation during those three years. This is different from the Pioneer ACO approach. The Pioneer benchmark (called the "baseline" in the Pioneer program) looks at a three-year claim history for the beneficiaries who are assigned ("aligned" in Pioneer terminology) in each performance year. The baseline reflects the care received by the beneficiaries, regardless of where they received that care in the past. In the final ACO regulations, the benchmark is based on claims that are representative of the care provided by the ACO's participants in the past, but not necessarily care provided to the current year's beneficiaries. The Pioneer approach reflects prior care received by today's beneficiaries. The final regulations look at prior care provided by the ACO's participating providers. CMS will evaluate the two approaches, and may adopt the Pioneer approach for all ACOs at some future date.

Data from each year will be trended forward to the third year of benchmark claim data (BY3), using the national average percentage trend in Medicare claims. This converts all claims data into BY3 dollars.

The claim data are also risk adjusted, using the Medicare Advantage risk adjustment model (CMS-HCC). Claims are adjusted to the BY3 risk score.

In calculating the benchmark, the oldest data, from BY1, will be weighted at ten percent. BY2 will be weighted at thirty percent. BY3 will be weighted at sixty percent.

The historical claim data will be separated into four groups, based on enrollment status of the beneficiaries, prior to trending and risk adjustment. The groups are:

- ESRD: Originally eligible for Medicare due to end-stage renal disease
- Disabled: Originally eligible for Medicare based on disability rather than age
- Aged dual-eligibles: Originally eligible for Medicare due to age, and also eligible for Medicaid
- Aged non-dual: Everyone else.

Each of the four groups will be trended by a percentage trend factor unique to that group. And each group will be risk-adjusted separately. The benchmark, expressed in adjusted BY3 dollars, is the average of the three years' data, weighted by the number of beneficiaries in each group, and adjusted to BY3 risk levels.

Under the final rule, the benchmark and per capita expenditures for the performance year will use a three-month run-out with a completion factor rather than the six-month claims run out in the proposed rule.

In a significant change from the proposed rule, indirect medical education payments to hospitals, and payments to disproportionate share hospitals (those with a large Medicaid census) will be excluded from calculation of the benchmark, and from each performance year's

cost calculation. This removes a disincentive to use teaching hospitals and safety net hospitals, which was a criticism of the proposed rule.

When CMS calculates the benchmark, and each year's costs, it will truncate each person's claims at the 99th percentile for all Medicare beneficiaries. This means that claims in excess of approximately $100,000 for any given beneficiary will be disregarded. This amounts to specific reinsurance stop-loss. The "premium" for this reinsurance equivalent is the amount by which the benchmark is reduced. This is almost certainly the least expensive approach available for an ACO to acquire stop-loss protection.

Once the benchmark is calculated, it will be updated annually during the agreement period by adding to each group's benchmark the fixed-dollar increase in the average per capita cost for each of the four enrollment groups.

The benchmark will be risk adjusted every year to account for the CMS-HCC scores of beneficiaries who are newly assigned to the ACO. However, CMS is not going to make an equivalent adjustment for any increase in risk scores for continuously assigned beneficiaries.

Continuously assigned beneficiaries are those who either were assigned to the ACO in the prior year, or who received at least one primary care service from an ACO participant within the prior year. CMS is concerned that ACOs will be able to improve the accuracy of diagnostic coding for their continuing beneficiaries. While it is a good thing to improve the validity of information in the claim database, CMS believes that this is also likely to inflate risk scores based on accuracy rather than actual changes in risk and disease burden.

CMS will monitor risk scores for continuing beneficiaries, and will make a downward adjustment if scores go down for this population from one year to the next. While a reduction in score could be the result of an actual reduction in risk, it could also result from poor coding practices that miss diagnoses or understate complications. Accountable Care Organizations will need to be vigilant to make sure their participants are coding properly to avoid losing credit for real savings, or having to pay for losses, that result not from their success or shortcomings in care management, but from coding inaccuracies.

TRACK ONE SHARED SAVINGS MODEL

In Track 1, ACOs will receive up to 50% of any savings they generate. Savings are defined as the amount by which total Medicare claim costs for assigned beneficiaries are less than the benchmark, after the benchmark has been trended and risk adjusted as described above.

In the proposed rule, Track 1 did not impose any down-side risk for losses until the third performance year. The final regulations eliminate downside risk entirely from Track 1. As in the proposed rule, Track 1 is only available for the initial agreement period. All Track 1 ACOs must convert to Track 2, with downside risk, if they want to renew their ACO agreements for another three-year period. The net impact of this change is to postpone down-side risk by one year.

As in the proposed rule, a Track 1 ACO must meet a minimum savings rate (MSR) in order to share in savings. The MSR is intended to avoid paying awards based on statistical fluctuation. CMS assumes that any savings that is less than the MSR is a statistical fluke. The MSR for Track 1 ACOs will vary depending on the size of the ACO. The smallest ACOs, between 5,000 and 6,000 assigned beneficiaries, which will have the greatest statistical variability in their data, must show savings that exceed 3.9% of their benchmark in order to receive a share in

their savings. The largest Track 1 ACOs, with over 60,000 beneficiaries, will need savings that exceed two percent of their benchmarks.

Track 1 ACOs will receive up to 50% of the savings they generate. They will share in the first dollar of savings. The proposed rule's two percent "vigorish" in the form of a guaranteed saving payment off the top, has been dropped. The savings share will vary as an ACO's quality score varies. The actual saving rate will be 50% multiplied by a fraction that equals the ACO's quality score divided by the maximum possible score. An ACO with a quality score that is 80% of the maximum possible quality score would receive 40% of any savings it generates, assuming that its savings exceed the MSR designated for its number of beneficiaries.

The maximum amount a Track 1 ACO may receive in payments is ten percent of the benchmark. For instance, if a Track 1 ACO achieved 20% savings relative to its benchmark, and had a perfect quality score that earned it the full 50% share, it would hit the maximum payment of 10% of the benchmark. It would receive no credit for any additional savings. The limit in the proposed rule was 7.5%.

In the proposed rule, CMS was going to withhold 25% of any earned savings payments, as a hedge against future losses, and to discourage ACOs from terminating their contracts before a full three-year term had run its course. This provision has been dropped from the final rule.

TRACK TWO SHARED SAVINGS MODEL

In Track 2, an ACO may receive up to 60% of any savings it produces. Savings are calculated in the same way as for Track 1 ACOs.

Track 2 is a two-sided model, in which ACOs will have to repay to CMS a percentage of any losses. Losses are defined as the amount by which the total cost to Medicare in any given year, for all assigned beneficiaries, exceeds the annual benchmark for that year multiplied by the number of beneficiaries. In calculating the loss, the benchmark will be trended and risk adjusted as described above. As in the proposed rule, an ACO's share of losses is the inverse of its share of savings. That is, the loss share rate is equal to one minus the corresponding savings sharing rate. For instance, if an ACO has a quality score that is 80% of the maximum possible, it's savings rate will be 60% times 80%, or 48%. Its loss share will be one minus the savings rate, or 52%. Because low quality scores could produce very high loss sharing rates, the final regulations place a 60% limit on the loss sharing rate.

Unlike Track 1, the MSR for Track 2 is a fixed amount, 2%, regardless of the number of assigned beneficiaries. Track 2 also has a minimum loss rate of 2%. Any savings or losses within plus or minimum 2% of the benchmark will be ignored. If the savings or loss is outside the 2% corridor, then the ACO shares in the first dollar savings or losses.

Total savings payments to a Track 2 ACO may not exceed 15% of the benchmark. This is an increase from the proposed rules' limit of 10%. The maximum loss a Tack 2 ACO will be required to remit to CMS is limited to 5% of the benchmark in the first year. The maximum loss payment increases to 7.5% in the second year, and to 10% thereafter.

While the proposed rule would have required ACOs to pay any loss penalty within thirty days of being notified of the amount due, CMS has decided to give ACOs 90 days to pay. And, as noted in Track 1, Track 2 ACOs will not see any of their savings share withheld against potential future losses.

INTERIM PAYMENTS

Because the first ACOs, those that start in April or July of 2012, will have an initial "performance year" that covers eighteen to twenty one months, the final rule makes provision for an interim payment during this initial long year. An ACO with a long initial year may request that CMS calculate a provisional savings or loss at the end of the first twelve months, with a final reconciliation when the full performance year is finished.

Under the interim payment method, CMS will determine shared savings and losses based on the first 12 months of experience, using the CY 2012 GPRO quality data as an interim proxy for the full quality data set.

Final reconciliation will occur after the completion for the ACO's first performance year defined as 21 months for April 1 starters and 18 months for July 1 starters. Quality reporting based on all quality measures will be used for the final reconciliation. The preamble describes the methodology to adjust the interim payment to account for the six or nine months included in CY 2012 and summing it for the CY 2013 performance. The reconciled amount of shared savings or losses will be net of any interim payments.

OTHER PAYMENT-RELATED FEATURES

The proposed rule would have increased the maximum share of savings for ACOs in which a significant percentage of beneficiaries received care from a FQHC or RHC. Now that CMS has figured out how to include health centers' patients in the assignment process, they do not believe that this incentive is necessary, and it has been dropped from the final rule.

As in the proposed rule, there is no incentive to serve dually eligible Medicare-Medicaid beneficiaries. However, CMS notes that the Center for Medicare and Medicaid Innovations, which is running the Pioneer ACO program, may sponsor a demonstration project for dual eligibles in the future.

The final rule continues the proposed rule's prohibition of double-dipping. No provider may participate in both an ACO and another CMS program that pays providers on the basis of shared savings, to avoid the potential to pay twice for the same savings. However, this does not preclude providers from participating in more than one ACO. CMS notes that claim data for providers that are not exclusive to a single ACO cannot be used to assign beneficiaries, but that the final rule does not require any provider to be exclusive.

The requirement for a repayment guarantee has been simplified. The requirement applies to two-sided Track 2 ACOs, and to any Track 1 ACO that receives an interim payment (since repayment may be required upon final reconciliation). ACOs will now be required to demonstrate that they are prepared to repay timely up to 1% of their annual benchmark, multiplied by the number of assigned beneficiaries. Proof of ability may include any of the following: reinsurance, escrow, surety bond, line of credit evinced by an irrevocable letter of credit upon which CMS may draw, or any other mechanism satisfactory to CMS.

An ACO with a net loss during its first agreement period will be allowed to participate for a second three-year period. However, it will need to describe how it intends to turn losses into gains during the second performance period.

DATA SUBMISSION AND CERTIFICATION

The ACO is ultimately responsible for data that is reported from all ACO operations. This responsibility extends to data that comes from ACO participants, provider/suppliers and any entity that furnishes services related to activities of the ACO. CMS will specify the form and manner that ACOs must use to submit data and information to CMS.

With each data submission, an official of the ACO with authority to bind the ACO must certify the veracity and completeness of the submission. An annual certification is also required for all information submitted including quality data and financial results that determine shared savings or losses or monies owed to CMS. The official certifies the accuracy, completeness, and truthfulness of the submission to the best of their knowledge, information and belief.

False Claims Act violations occur when information is known to be false. With this language, officials are noting that they are not knowingly submitting false information with actual knowledge of its falsity. FCA prosecution can also occur if it is determined that the official should have known the information was inaccurate.

ACO QUALITY PERFORMANCE MEASURES

The final rule establishes quality performance measures to assess the quality of care furnished by the ACO. If the ACO meets the quality performance measures and other applicable requirements, the ACO is eligible for shared savings.

The final rule reduces the number of domains from 5 to 4 by combining the proposed care coordination and patient safety domains into one domain in the final rule. The quality measures are reduced from 65 measures in the proposed rule to 33 measures. All measures in Year 1 will be pay for reporting. Year 2 will include eight measures as pay for reporting and 25 measures as pay for performance. In Year 3 only one measure will be pay for reporting.

The preamble includes a list of all 33 measures and discusses the rationale for why some measures were retained and some dropped. Of the final 33 measures, seven are collected by survey, three are calculated from claims, one is calculated from the EHR incentive program data and 22 are collected via the GPRO web interface. In general, the final measures focus on patient experience, outcomes and evidence-based care processes. The final measure set focuses on prevention and management of chronic diseases that have a high impact on beneficiaries such as heart disease, diabetes and COPD. The set focuses on discrete processes and short term measurable outcomes. The final set focuses on ambulatory care consistent with primary care.

The final rule eliminates measures that were duplicative, or focused on hospitals which may not be included in many ACOs. The final rule retained measures that were aligned measures with PQRS and the EHR Incentive Program. Assessment will include care received from ACO providers and non-ACO providers. Quality measures will have a 12-month calendar year reporting period regardless of the start date.

The final rule will aggregate the four quality domain scores (patient/caregiver experience, care coordination/patient safety, preventive health, and at-risk population) and measures within each domain equally into a single overall ACO score used to calculate the ACO's final sharing rate. The only exception is the EHR measure which will be double weighted for scoring purposes.

The at-risk disease categories include: diabetes, hypertension, ischemic vascular disease, heart failure and coronary artery disease.

The final rule includes a sliding scale measure scoring approach where the percentile level of the ACO performance-level benchmark translates to a number of Quality Points. The preamble includes a chart displaying the sliding scale measure scoring approach. The final rule retains a minimum attainment level for a measure at a national flat 30 percent or, where applicable, the national 30th percentile level of performance of FFS or MA quality rates. ACOs would earn their maximum sharing rate for accurately reporting 100 percent of the required data. ACOs that fail to achieve quality performance on 70 percent of the measures in each domain will be placed on a corrective action plan and re-evaluated the following year.

If the ACO continues to underperform the agreement will be terminated. In any year that the ACO scores zero for an entire measure domain, it would be ineligible to share in any savings. If the ACO fails to report the EHR measure, it would miss the 70 percent cutoff. The total potential for shared savings is higher under the two-sided model because the maximum sharable savings based on quality is 60 percent, compared to 50 percent under the one-sided model.

The scale will reward greater improvement over time. For future performance periods, the percent of shareable savings will vary based on the ACO's performance on the measures as compared with the measure benchmarks. The final rule will establish national benchmarks for quality measures, which will be phased in using a national sample of FFS and MA quality data, or a flat percentage if these data are not available.

The measures are generally risk adjusted by age and gender, although some measures are specifically risk adjusted (e.g., all condition readmission measures and ACSC). The quality measures include a percentage of primary care providers who successfully qualify for an EHR incentive program payment rather than the meaningful use measure included in the proposed rule. CMS will use the CG-CAHPS survey and score the individual modules as one measure. CMS will pay for the survey in 2012 and 2013 to assure standardized administration. In 2014, the ACO must select a CMS-approved vendor and pay for the survey. The measure set includes an access-to-specialists module to align with the step-wise assignment method. The final rule corrects the proposed rule list to include NQF #97, which is a 60-day post discharge medication reconciliation measure.

In the final rule, CMS will allow an ACO to receive the PQRS incentive payments, provided it participates as a group practice without conditioning this payment on the reporting of all of the other ACO quality measures. The ACO can qualify as a group practice for the Physician Quality Reporting System (PQRS) incentive payment. The PQRS incentive payment is 0.5 percent of the ACO's eligible professional total estimated Part B physician fee schedule allowed charges.

CMS requires ACOs to certify the accuracy and completeness of quality data and will include a process to audit quality measure data. The CMS audit consists of three phases of medical record review. If there is a discrepancy greater than 10 percent between the quality data reported and the medical records provided, the ACO will not be given credit for meeting the quality target for any measures that do not match.

IMPACT ON STATES

The preamble of the final rule indicates that the states should not bear any costs resulting from the operation of the Shared Savings Program. The Medicare program retains the insurance risk and responsibility for paying claims for services furnished to Medicare beneficiaries and the agreement to share potential losses is solely between the Medicare program and the ACO.

BENEFICIARY PROTECTIONS AND MARKETING MATERIALS

BENEFICIARY NOTIFICATION

CMS will develop a communication plan to include updates to the Medicare Handbook and other educational materials and outreach, and to explain the ACO program to beneficiaries. In the final rule, CMS stated they will incorporate the requirements of the Plain Writing Act of 2010 in all CMS communications and standard language regarding the Shared Savings Program. ACOs also have an important role in notifying beneficiaries.

The ACO must notify beneficiaries at the point of care that their ACO providers/suppliers are participating in the Shared Savings Program. All participants will be required to post signs in their facilities and make available standardized written notices in settings where beneficiaries receive primary care services. CMS expects that information will promote discussion with beneficiaries about the aims of the program and more completely engage the beneficiary in their care. Conversely, the ACO and its participants will not be required to notify beneficiaries when they will no longer participate in the Shared Savings Program.

Alternatively, under the final rule, ACOs can provide notification about their participation in the Shared Savings Program to beneficiaries who appear on the preliminary prospective alignment list or quarterly assignment list. Beneficiaries would be given 30 days to opt out of having their claim information shared with the ACO. CMS will develop and provide this template notification.

MARKETING MATERIALS

CMS has defined marketing materials for ACOs as well as activities for communication with beneficiaries. The use or purpose of any material identifies materials or activities that are defined as marketing. These purposes include educating, soliciting, notifying or contacting a beneficiary about the Shared Savings Program. The definition covers all beneficiaries, whether they are served by the ACO or not. The definition also includes use of these materials for communication with or marketing to providers or suppliers. CMS also applies the definition to other activities conducted by or on behalf of the ACO, ACO participants, and/or ACO providers/suppliers participating in the ACO.

While CMS identifies specific types of materials, CMS notes that the definition is not limited to the listed types of materials. These include:

- General audience materials such as brochures;
- Advertisements;
- Outreach events;
- Letters to beneficiaries;
- Web pages;

- Data sharing opt out letters;
- Mailings;
- Social media

Other materials with the purposes noted above will be subject to marketing oversight.

Additionally, CMS has defined materials and activities that are not marketing materials and activities.

These include:

- Certain informational materials customized or limited to a subset of beneficiaries;
- Materials that do not include information about the ACO, its ACO participants, or its ACO providers/suppliers;
- Materials that cover beneficiary-specific billing and claims issues or other specific individual health related issues;
- Educational information on specific medical conditions ;
- Written referrals for health care items and services;
- Materials or activities that do not constitute "marketing" under 45 CFR 164.501 and 164.508(a) (3) (I).

MARKETING MATERIAL OVERSIGHT

CMS will follow a file and use process for ACO materials and activities. The ACO must certify that the materials meet all marketing requirements and must allow for a five-day period to elapse before using the submitted materials. During the five-day period, CMS may review and disapprove the materials. Otherwise, the materials are deemed approved after the five-day period. Finally, CMS may, anytime in the future, determine that the materials are non-compliant and disapprove the materials, requiring the ACO or any entity using the materials to cease use of the materials.

MARKETING REQUIREMENTS

1. CMS will develop template materials that ACOs will be required to use when available.

2. ACOs cannot conduct any marketing that is discriminatory or has the intent to discriminate.

3. ACOs cannot use inaccurate or misleading materials.

INDUCEMENTS TO BENEFICIARIES

The ACO, its participants and its providers/suppliers are prohibited from offering gifts, cash or other remuneration as an inducement to receive services of the ACO or remain in the ACO with a specific provider.

However, the ACO may offer free services or discounts from market value to encourage coordination of care and beneficiary health awareness.

To offer these inducements:

- The ACO must be in good standing under its participation agreement;
- There must be a reasonable connection between the services and the medical care of the beneficiary

The services must be in-kind and either preventive care items or services or advance adherence to a treatment regime, drug regime, follow-up care or management of a chronic disease or condition.

COMPLIANCE PLAN

ACOs are required to have a compliance plan that has methods for identifying and addressing compliance problems and methods for employees, ACO participants and providers/suppliers and other individuals to anonymously report suspected problems. Compliance training must be provided to the ACO, ACO participants and ACO providers/suppliers. Of particular note, the compliance officer cannot also serve as the legal counsel to the ACO and must report directly to the ACO's governing body. Additionally, the ACO is required to report probable violations of law to an appropriate enforcement agency. The final rule requires compliance plans to be updated to reflect changes in law and regulations.

MONITORING, SANCTIONS AND TERMINATIONS

AUDITS AND RECORD RETENTION

CMS will monitor ACOs through a variety of tools to assess the performance of ACOs, ACO participants and ACO provider/suppliers. CMS will use an analysis of specific financial and quality data that the ACO reports, beneficiary complaints and audits.

AUDITS

For auditing, specific regulatory requirements stipulate that CMS, DHHS and other Federal government agencies have a right to audit the ACO, its participants and providers/suppliers, and any other individuals who serve the ACO. The focus of the audits will be compliance with the Share Savings Program, quality of services and the amount due to or from CMS under the participation agreement and the ability of the ACO to bear risk of loss and repay any losses. Audits can result in a reopening of an earlier determination and issuance of a revised initial determination.

RECORD MAINTENANCE

In concert with the audit requirement, ACOs must retain records for a period of ten years from the final date of the ACO contract. The government can also require a later date by providing notice. If there has been a termination, dispute or allegations of fraud against the ACO, the ACO must retain records for six years from the point of resolution of the issue. The regulation provides a list of record types that includes almost all or any record of activity conducted in the ACO program. The regulation also notes that the ACO is ultimately responsible for this requirement, notwithstanding any arrangements that are made with ACO participants or providers/suppliers, so that the government would expect to obtain any record that is maintained

by an ACO participant or provider/supplier.

MONITORING AVOIDANCE OF AT-RISK BENEFICIARIES

Given the statutory identification of "patients at-risk" as a reason for taking adverse action, CMS must monitor marketing and services provided to at-risk beneficiaries to identify any trends or patterns that indicate the ACO has avoided at-risk beneficiaries. Monitoring will focus on under-utilization by ACO members as well as over-utilization of services furnished to beneficiaries not assigned to the ACO. CMS will initiate further investigation and audits if information indicates that the ACO has avoided at-risk beneficiaries.

An at-risk beneficiary is defined as a beneficiary who:

- Has a high risk score on the CMS-HCC risk adjustment model;
- Is considered high cost due to having two or more hospitalizations or emergency room visits each year;
- Is dually eligible for Medicare and Medicaid;
- Has a high utilization pattern;
- Has one or more chronic conditions;
- Has had a recent diagnosis that is expected to result in increased cost;
- Is entitled to Medicaid because of disability;
- Is diagnosed with a mental health or substance abuse disorder;

The last two categories of "at-risk beneficiaries" were added in the final rule.

If CMS determines that the ACO has avoided at-risk beneficiaries, CMS can take adverse action to immediately terminate the ACO from the program. As an alternative measure, CMS could require the development of a corrective action plan (CAP). During the period that the ACO is under a CAP, the ACO will not receive shared savings payments and will not be paid for any periods that occurred before the CAP when the ACO avoided at-risk beneficiaries. CMS will evaluate the ACO performance during and after the CAP. If avoidance behavior continues, the ACO will be terminated.

MONITORING QUALITY PERFORMANCE STANDARDS

For monitoring quality standards, CMS will evaluate annual submission of performance against each domain. If the ACO fails to meet minimum standards in one or more domains, CMS will send a warning letter to the ACO. However, CMS may forego sending a warning letter if conditions warrant the development of a CAP or immediate termination. Failure to achieve improvement will result in termination at the end of the next year.

CMS will require submission of all required data. An ACO that fails to submit required data must provide a written explanation for the failure to provide data. Failure to provide sufficient reason for the failure to submit data or an inability to fulfill the requirement within a specified time period will result in immediate termination. Given that meeting quality standards is a condition of shared savings, ACOs that show a pattern of providing inaccurate, incomplete or late reports could result in disqualification from participation in shared savings each year the ACO underperforms.

CORRECTIVE ACTION PLANS

For minor violations and those that pose no immediate risk or harm to beneficiaries or impact on care, ACOs can submit a corrective action plan to avoid termination, which CMS must approve. However, CAPs can also be requested for specific failures to provide quality data or avoidance of at-risk beneficiaries. During these latter two CAP periods, ACOs are not eligible for shared savings.

RECONSIDERATIONS

Applicant ACOs and ACOs that are subject to termination procedures can request reconsideration of an adverse determination. Of particular note: the ACA prohibits any judicial or administrative appeal for several actions, including the criteria for quality performance standards; assessment of quality furnished by the ACO; assignment of beneficiaries to the ACO; eligibility for or the amount of shared savings as well as the percent of shared savings; and finally, termination for failure to meet quality performance standards.

A reconsideration request can be made for denied applications and terminations. The process requires submission of the request for reconsideration within 15 days of the notice. CMS provides an independent review of the initial determination and the ACO must provide evidence that the CMS determination was incorrect. An independent reviewer who was not involved with any previous determination conducts the reconsideration. If the reconsideration decision upholds the initial determination, the ACO may request an on-the-record review of the initial reconsideration. CMS may also request a review of this determination. With the second reconsideration determination, the decision will be the final CMS determination.

PROGRAM INTEGRITY

SCREENING OF APPLICANTS

CMS will screen the program integrity history of ACO applicants, ACO participants and ACO providers/suppliers to determine if there is a history of program exclusions or other sanctions. This will include a review of affiliations with individuals or entities that have a history of program integrity issues. For the most part, this review will involve entities that are not eligible to enroll in Medicare, as entities eligible to enroll in Medicare would have been subjected to required enrollment screens. CMS will perform screening during the application process and periodically thereafter.

When program integrity issues are identified, CMS must determine if the application will be rejected or if additional safeguards will be required to address the increased risk of fraud and abuse. This could require a CAP for operational ACO entities.

PROHIBITION ON CERTAIN REQUIRED REFERRALS AND COST SHIFTING

To prevent ACOs from offering inducements to over-utilize services in other Federal health care programs or services to beneficiaries not assigned to the ACO, the regulation prohibits ACOs from requiring any ACO participant, provider/supplier of any other entity to provide referrals for other Federal health care business that would be performed by the ACO or any of its participants or providers/suppliers. CMS recognizes the potential for cost-shifting behavior to Part D for drugs covered under Part B and will analyze drug utilization under these programs.

CMS recognizes that commercial arrangements are outside of the authority of these regulations where cost shifting can occur. CMS expects to monitor these issues and will work in consultation with the Federal Trade Commission, Department of Justice and the HHS OIG when inappropriate patterns of cost-shifting occur.

Finally, the regulations ensure beneficiaries' freedom of choice in the Medicare fee-for-service program. ACOs cannot require that beneficiaries be referred only to ACO participants or provider/suppliers. However, employees of ACOs can exclusively refer to ACO providers if they are free to make referrals without restriction when the beneficiary, their insurer or the referral party determines that the referral is not in the best medical interests of the beneficiary.

CONTRACT TERMINATION

Termination of an ACO contract can occur at any time during the three-year contract period. While termination can occur for avoiding at-risk patients and failure to meet quality standards, termination can occur for a variety of others reasons. These include failure to continue to meet eligibility requirements such as maintenance of the minimum 5,000 beneficiary threshold, lack of a formal legal structure, failure to notify beneficiaries, failure to demonstrate meaningful beneficiary participation and failure to meet regulatory requirements for operations or to complete corrective actions. Termination can also result from submission of false data, violations of anti-kickback rules, anti-fraud or anti-trust laws and failure to submit payments due to CMS in a timely manner and finally, use of unapproved marketing materials or activities or other beneficiary communications.

At its discretion, CMS will use warning letters and CAPs to address non-compliance. However, termination can be immediate for serious infractions. Otherwise, termination occurs after a 60-day period. Termination by ACO request will require the ACO to provide notice to CMS and all ACO participants. The ACO will not share in any savings for the performance year in which it notifies CMS of its termination decision. Finally, the ACO is not required to notify beneficiaries of its decision to withdraw from the Shared Savings Program.

REAPPLICATION AFTER TERMINATION

Accountable Care Organizations that have been terminated are not eligible to participate in the ACO program until the period of the initial participation period has expired. ACOs terminated for non-compliance, will not be allowed to re-apply without providing evidence of corrective action taken to address non-compliance as well as safeguards that will ensure the ACO can participate for the full period of its agreement.

Accountable Care Organizations that were in the one-sided program will be allowed to re-enter the one-sided program if less than half of their initial agreement period had expired while all other ACOs will be re--admitted into the two-sided program. In either case, readmission will not occur until after the expiration date of their initial agreements.

CMS DATA

CMS will share data with ACOs including aggregate historical data used to calculate the benchmarks at the beginning of the performance period and quarterly thereafter. CMS will also share beneficiary specific information for purposes of care coordination, improving health or reducing costs following HIPPA requirements. All data sharing must comply with

HIPAA privacy and security rules, and the ACO must sign a data use agreement with CMS. The proposed rule specifies minimum necessary data from Parts A, B and D. The ACO must provide beneficiaries with an opt-out form as part of an office visit with a primary care physician.

ADVANCE PAYMENT ACO MODEL

In conjunction with issuing the final Shared Savings ACO rule, CMS announced the Advance Payment ACO Model. A copy can be found online at http://innovations.cms.gov/documents/payment-care/APACO_Solicitation_10_20_11_Compliant1.pdf

Under the Advance Payment ACO Model up to 50 participants in the Shared Savings Program can receive assistance with the capital necessary to build and operate an ACO. Up to $170 million is available for advance payments of which 60 percent will be available to ACOs with a Shared Savings Agreement beginning April 2012, and 40 percent for ACOs whose agreement begins July 2012.

The advance payments will be recouped from the shared savings as part of the mid-2014 settlement. If the savings are not sufficient, the balance will be recouped in the subsequent two years. ACOs that do not complete the full initial agreement period will repay the full amount. ACOs that do not enter a second agreement period will not have to pay any remaining advance payments.

The selected rural and physician owned ACOs eligible to apply for Advance Payments include:

- ACOs that do not include any inpatient facilities and have less than $50 million in total annual revenue;
- ACOs in which the only inpatient facilities are critical access hospitals and/or Medicare low-volume rural hospitals and have less than $80 million in total annual income.

Annual revenue is the total revenue of all ACO providers and suppliers (including the revenue of owners of ACO participants) averaged over the most recent three year period. ACOs that are co-owned with a health plan that meet these criteria will not be eligible to apply.

The Advance Payments include:

- $250,000 in the first month of the performance period
- An up-front variable payment of $36 for each assigned beneficiary
- A variable monthly payment of $8 for each assigned beneficiary

Applicants must apply for the Shared Savings Program first and then complete the Advance Payment application. As part of their application for advance payments, ACOs must submit a spending plan on how they plan to use the advance payments for operating costs and to build care coordination capabilities. Selection criteria will favor ACOs with the least access to capital, ACOs that serve rural populations, and ACOs that serve a significant number of Medicaid beneficiaries.

HHS OFFICE OF THE INSPECTOR GENERAL: WAIVER DESIGNS FOR ACOs

Notice can be found online at http://www.ofr.gov/OFRUpload/OFRData/2011-27460_PI.pdf

FRAUD AND ABUSE WAIVERS FOR MEDICARE ACOs

CMS and the OIG released the interim final rule that provides waivers to three laws that protect federal health programs from fraud, improper referral payments, unnecessary utilization and under utilization. The waivers apply uniformly to each ACO, ACO participant, and ACO provider/supplier. They are intended to be self-implementing. No special action or separate application is required in order to be covered by a waiver. However, ACOs must proceed in a deliberate fashion by reviewing the arrangements they will make to ensure that their arrangements will remain within the scope of the waivers that apply.

There are five waivers for operation of the ACO program:

1. Pre-participation: This is a waiver of the Physician Self-Referral Law, the Federal anti-kickback statute, and the Gainsharing CMP that applies to ACO-related start-up arrangements in anticipation of participating in the Shared Savings Program.

2. Participation: This is a waiver of the Physician Self-Referral Law, the Federal anti-kickback statute, and the Gainsharing CMP that applies broadly to ACO-related arrangements during the term of the ACO's participation agreement under the Shared Savings Program.

3. Shared Savings Distribution - This is a waiver of the Physician Self-Referral Law, Federal anti-kickback statute, and Gainsharing CMP that applies to distributions and uses of shared savings payments earned under the Shared Savings Program.

4. Compliance with the Physician Self-Referral Law: This is a waiver of the Gainsharing CMP and the Federal anti-kickback statute for ACO arrangements that implicate the Physician Self-Referral Law and meet an existing exception.

5. Patient incentive: This is a waiver of the Beneficiary Inducements CMP and the Federal anti-kickback statute for medically related incentives offered by ACOs under the Shared Savings Program to beneficiaries to encourage preventive care and compliance with treatment regimes.

Each waiver has conditions that limit their applicability to ACOs, time periods for operation, and required documentation. These conditions ensure that CMS and OIG can distinguish ACOs in communities whenever government agencies or others question activities by and between providers who could, in fact, have illegal arrangements.

PRE-PARTICIPATION AND PARTICIPATION WAIVERS

This Pre-Participation waiver protects the ACO investment in start-up, operating and other arrangements that the ACO must engage in to develop the ACO. Start-up could apply to any items, services, facilities or goods that are provided by the ACO, ACO participants or providers/suppliers. While a list of these items is provided, CMS notes that the list is

not exhaustive and other items may be included. However, CMS notes that any item that is considered acceptable must be considered a bona fide start-up arrangement. At the same time, the participation waiver covers these arrangements and any additional items that meet requirements. It is noteworthy that the waiver excludes drug and device manufacturers, distributors, DME suppliers, and home health suppliers.

There are additional safeguards in the form of governance responsibility, transparency, and a documented audit trail. Also, the duration of the waiver sets timing for planning for ACO arrangements as well as timing for untangling arrangements at the end of the application process or termination of the ACO.

1. The ACO governing body must make a bona fide determination that the arrangement is reasonably related to the purposes of the Shared Savings Program. This ensures that the governing body becomes the intermediary responsible to ensure that arrangements are for the ACO and are not isolated arrangements furthering financial or business interests of ACO participants or providers/suppliers.

2. The expectation is that there is due diligence in making these determinations and that the reasons supporting them are documented. The ACO must develop each waiver with an audit trail of the documentation that describes the core characteristics of the arrangement and clearly explains its terms. Finally, documentation must show the steps taken to develop the arrangement and the expectation is that this documentation is produced as the ACO is developing its arrangements. Documentation should not be developed on the basis of recall of the events.

3. Transparency in development of the arrangement is crucial to ensuring that secrecy is unnecessary to protect hidden arrangements, information is readily available to parties in the ACO and the effort to exercise due diligence in developing compliant arrangements receives greater focus. Until a process for disclosure is developed, CMS expects this information to be posted to a public website associated with the ACO or an entity forming the ACO.

4. The parties developing the ACO must make diligent steps to develop the ACO during a target year.

   - For contract year 2012, the waiver is in-place with the publication of the interim rule and for later years it would begin one year before the due date for new ACO applications.
   - The waiver actually stays in place until the start date of the contract when it becomes a participation waiver and remains in place until it expires six months after the termination of the ACO agreement. However, if CMS terminates the agreement, the waiver ends with the termination.
   - For denied applications, the waiver ends with the denial notice but protection extends six months from the denial notice and no new arrangements could be approved in that time period.
   - For entities that fail to submit an application, the waiver period ends on the due date of the application and these entities must submit a letter to HHS describing the reasons for its failure to submit an application. These entities may apply for an extension of the waiver if they are likely to submit an application for the next year.

WAIVER FOR SHARED SAVINGS DISTRIBUTIONS

The waiver for shared savings distributions protects arrangements created by the distribution of shared savings within an ACO, as well as arrangements created by the use of shared savings to pay outside parties for services reasonably related to the Shared Savings Program. This waiver permits shared savings to be distributed or used within the ACO in any form or manner, including "downstream" distributions with the ACO, its ACO participants, and its ACO providers/suppliers.

This waiver is limited to amounts from shared savings. Other arrangements would need to qualify for other waivers, safe harbors or comply with the laws. Distributions of shared savings to referring physicians outside the ACO must be compensation for activities that are reasonably related to the Shared Savings Program or to physicians who were previously ACO participants or ACO providers/suppliers. Finally, the waiver does not protect gainsharing payments that compensate a physician to reduce or limit medical care without providing acceptable alternative medically necessary care.

COMPLIANCE WITH THE PHYSICIAN SELF-REFERRAL LAW WAIVER

This waiver protects arrangements that are operating during the period of the participation agreement. It begins with the start date of the participation agreement. The end date will be specified in the participation agreement and will allow a period of time to unwind financial relationships and re-structure them. However, if CMS terminates the ACO, the waiver will end at the termination date. In many cases, arrangements meet current requirements and comply with the physician self-referral rules. This waiver allows that providers who have compliant relationships are not required to undertake a separate review to establish their compliance under the ACO. Also, this waiver allows that additional reviews of these arrangements for compliance with the Federal anti-kickback and the Gainsharing CMP are not necessary to carry out the Shared Savings Program.

WAIVER FOR PATIENT INCENTIVES

This waiver will help ACOs foster patient engagement in improving quality and lowering costs for Medicare and beneficiaries by removing any perceived obstacles presented by the Beneficiary Inducements, CMP or Federal anti-kickback statute. The goal of the waiver is to allow ACOs to provide beneficiaries with free or below-fair market value items and services that advance the goals of preventive care, adherence to treatment, drug, or follow-up care regimes, or management of a chronic disease or condition. Because the waiver is not limited to beneficiaries assigned to the ACO, beneficiaries not in the ACO can receive inducements that meet these conditions. However, there must be a reasonable connection between the incentives and the medical care of the individual.

The waiver will protect incentives that are in-kind items or services, but not financial incentives, such as waiving or reducing patient cost sharing amounts such as copayments or deductibles. ACOs, ACO participants, and ACO provider/suppliers are allowed to give beneficiaries items or services that they have received from manufacturers at discounted rates. However, the waiver would not cover the discount arrangement (or any arrangement for free items and services) between the manufacturer and the ACO, ACO participant, or ACO provider/supplier.

This waiver applies during the term of the ACO's participation agreement but a beneficiary may keep any items received during the term of the ACO's participation agreement and may continue to receive any service initiated during the term of the ACO's participation agreement if the service was in progress when the participation agreement terminated.

APPLICATION OF WAIVERS TO INNOVATION CENTER DEMONSTRATIONS

The waivers that are enacted under this interim rule are limited to the Shared Savings Program. However, CMS will issue future guidance on how these can be applied to demonstrations such as the Pioneer ACO demonstration.

FTC AND DOJ: ANTI-TRUST ENFORCEMENT POLICY

Policy statement can be found at: http://www.ftc.gov/opa/2011/10/aco.shtm

The FTC and DOJ (the Agencies) published a final policy statement on their policy for Accountable Care Organizations that will participate in the Shared Savings Program.

Overall Application of the Policy

First, the Agencies note that the policy will apply to all organizations that will participate in the Shared Savings Program. It will also be apply to the development of commercial ACOs. Second, the application of the policy is not limited to any specific date relating to the formation of the proposed ACO. Third, no organization will be required to seek a mandatory review as a condition of entry to the Shared Savings Program since CMS regulations governing the program no longer require mandatory review. However, CMS will provide data to the Agencies regarding allowed charges and fee-for-service payments for all ACOs to support the role of the Agencies in protecting competition in markets served by the ACOs. Finally, the Agencies will provide an expedited 90-day review to ACOs formed after 3/23/10 that wish to receive guidance on their formation.

The policy applies to collaborations of independent providers and provider groups that will constitute the ACO but it does not apply to mergers or fully integrated organizations.

Rule of Reason

In their oversight capacity, the Agencies will apply a Rule of Reason Analysis to the review of ACOs. This analysis will focus on a review of the actual facts involved in ACO development. First, regulations provide certain eligibility criteria that are indicative of clinical integration that is likely to produce desirable efficiencies. These criteria are consistent with the criteria for clinical integration that the Agencies have applied in previous cases and publications. Organizations meeting the CMS criteria for approval as an ACO are reasonably likely to be bona fide arrangements intended to improve the quality, and reduce the costs of providing medical and other health care services through their participants' joint efforts. Extensive monitoring of cost, utilization, and quality metrics by CMS will assist the Agencies in determining the extent to which the proposed CMS eligibility criteria in fact lead to cost savings and improved health care quality and may help inform the Agencies' future analysis of ACOs and other provider organizations. Given the eligibility criteria, and CMS monitoring of each ACO's results, the Agencies will treat joint private payers' negotiations as reasonably necessary to an ACO's primary purpose of improving health care delivery, and will afford rule of reason treatment to an

ACO that meets CMS's eligibility requirements.

Antitrust Analysis of ACOs

The Agencies recognize that health care providers seeking to create Medicare ACOs would like additional information on criteria for determining if their arrangements could be subject to an antitrust investigation.

The Agencies proposed an analysis that focuses on each ACO participant's share of services within their Primary Service Area. The higher the PSA share, the greater the risk the ACO will be anticompetitive. This could result in reduction in quality, innovation, and choice for Medicare and commercial patients as well as the ability to form competing ACOs. A high PSA share would allow the ACO to raise prices to commercial health plans above competitive levels. For making determinations about PSAs, the notice provides an appendix with available data sources for calculating an ACO's share of services.

Depending on an ACO's range of PSA shares, an ACO will be in the Safety Zone or they will be outside the Safety Zone. An ACO can send questions to the FTC regarding PSA share calculations. An ACO may choose to seek, an expedited antitrust review if they are outside the Safety Zone.

ACO Antitrust Safety Zone

ACOs that meet criteria for the safety zone are highly unlikely to raise significant competitive concerns. Consequently, the Agencies will not challenge ACOs that fall into the safety zone, absent extraordinary circumstances.

ACOs must determine their share of a common service for each of their ACO participants. To be classified in the safety zone, independent ACO participants that provide the same service must have a combined share of 30 percent or less of each common service in each participant's PSA. The PSA for each service is defined as the lowest number of contiguous postal zip codes from which the ACO draws at least 75 percent of the patients for that service.

Any hospital or ambulatory surgery center participating in an ACO must be non-exclusive to the ACO to fall within the safety zone, regardless of its PSA share. In a non-exclusive ACO, a hospital or ASC is allowed to contract individually or affiliate with other ACOs or commercial payers. The safety zone for physician and other provider services does not differ based on whether the physicians or other providers are exclusive or non-exclusive to the ACO, unless they fall within the rural exception or dominant provider limitation described below.

There is a Rural Exception and a dominant provider limitation, which allow an ACO to qualify for the safety zone criteria. Under these limitations, providers must be non-exclusive to the ACO. In addition, the ACO cannot require a commercial payer to contract exclusively with the ACO or restrict a commercial payer's ability to contract or deal with other ACOs or provider networks.

ACOs Outside the Safety Zone

ACOs that fall outside of the Safety Zone may not necessarily violate antitrust rules. The policy notes that PSA shares are useful as a screening device but that alternative data and information also may be useful in evaluating the likely competitive significance of a particular ACO. The Agencies recognize that an ACO may have reliable evidence other than PSA shares from which

the ACO may reasonably conclude that the ACO is unlikely to raise competitive concerns.

For these organizations, the policy identifies certain types of conduct that would raise competitive concerns. Organizations that engage in these activities may opt to seek antitrust guidance from the Agencies. While sharing sensitive information is highly suspect, other conduct may be competitively neutral.

1. Improper Sharing of Competitively Sensitive Information

   ACOs must avoid the appearance of activities that could facilitate improper exchanges of sensitive price information that can lead to price-fixing or collusion in the sale of services outside the ACO. ACOs should have appropriate firewalls or other safeguards that will prevent this conduct among participants.

2. Other Indicators of Market Power

   - Preventing or discouraging private payers from incentivizing patients to choose certain providers
   - Tying sales to purchase of other services from providers outside the ACO
   - Preventing or discouraging those providers from contracting with private payers outside the ACO
   - Restricting information to enrollees about cost, quality, efficiency, and performance that would in evaluating and selecting providers in the health plan

Voluntary Expedited Review

Any ACO can request antitrust guidance via a 90-day review from the Agencies. The focus of the review is to determine if the ACO will harm competition by raising prices and/or reducing output, quality, service or innovation.

To make a request, the ACO should provide documentation to both Agencies before its entrance into the Shared Savings Program. The documentation includes—

- ACO application with all supplemental materials
- ACO business strategies
- Level and nature of competition among participants in the ACO
- Sufficient information regarding PSA levels for ACO participants
- Restrictions to prevent sharing of pricing
- Identity and contacts for five largest commercial payers
- Identity of planned or actual ACOs
- Any information or justification that may assist the reviewing agency

The Agency will provide the report within 90 days. The report is made public along with the request letter. It will provide one of three responses.

1. Not likely to raise concerns
2. Potentially raises competitive concerns
3. Likely raises competitive concerns

IRS NOTICE

The IRS fact sheet can be found at http://www.irs.gov/newsroom/article/0,,id=248490,00.html.

The fact sheet confirms that Notice 2011-20 that was issued for comment continues to reflect IRS expectations. The IRS expects that CMS's regulation and oversight of the Shared Savings program will be sufficient to further the charitable purposes of lessening the burdens of government. The fact sheet also provides additional information for charitable organizations that want to participate in the Shared Savings program

The following is a brief summary of the IRS notice, and is not, in any way, intended to represent tax advice. A 501(c) (3) that is considering partial ownership of or participation with an ACO should have the proposed arrangement vetted by a competent tax lawyer. The IRS notice can be found at: http://www.irs.gov/newsroom/article/0,,id=248490,00.html

IMPACT OF ACO PARTICIPATION ON A 501(c) (3) TAX EXEMPT STATUS

The guidance is sufficient for 501(c) (3) entities that participate in Medicare ACOs or in other similar arrangements such as those sponsored by commercial and Medicaid insurance carriers.

The provision of health care services is not, *per se*, a charitable activity, although many activities that promote health have been deemed charitable. Tax exemption requires that an entity not be run for the benefit of insiders (owners and officers, generally). To be tax exempt, the entity must not devote more than an "insubstantial" amount of its activities to non-exempt purposes. One of the charitable purposes of tax exemption can include lessening the burdens of government. The IRS notes that PSROs were deemed tax exempt since their oversight of Medicare and Medicaid quality lessened a burden of government to do so.

In considering the impact of a tax exempt entity owning part of an ACO, the IRS cited a ruling that the activities of an LLC that was taxed as a partnership were considered to be activities of a tax exempt entity that was a member of the LLC. The entity's share of the LLC's net income would be treated and taxed as unrelated business income if the LLC's activities were not, themselves, for a tax exempt purpose.

An ACO may be a stock corporation, non-profit membership corporation, partnership, or LLC. A 501(c) (3) entity may participate as a member of the corporation or LLC, as an owner of stock, or under a participation contract. The tax consequences for the ACO and its tax-exempt partners will vary on the type of entity. However, there are no special federal income tax rules that apply to charitable organizations under the Shared Savings program. Generally the IRS does not expect a tax exempt participant's share of savings would not be subject to the unrelated business income tax (UBIT). Generally the IRS does not expect the non-Shared Savings program activities that do not further a charitable purpose to jeopardize its tax exempt participant.

The 501(c)(3) must ensure that its participation is structured in a way that avoids inurnment to its insiders. Arrangement between a 501(c)(3) and an ACO will not result in an impermissible private inurnment or private benefit if:

- The terms of participation are set forth in a written agreement and negotiated at arm's length
- The ACO has been accepted into the Medicare shared savings program by CMS and has not been terminated from the program
- The 501(c)(3) receives benefits from the ACO that are proportional to the benefits or

contributions the ACO receives from the entity (The IRS does not say whether medical care provided to beneficiaries assigned to the ACO will be counted in determining benefits provided to the ACO).

- The entity's ownership share, if any, is proportionate to its capital contribution;
- The entity's share of ACO losses does not exceed the share of economic benefits it is entitled to (This appears to mean that gains and losses are shared among the ACOs owners according to the same proportions).
- The ACO transacts business at fair market value.

Payments received from the ACO will not be taxed as unrelated business income if the ACO operates as set forth above.

The IRS notes that participation in an ACO that contracts with Medicaid may be related to activities that lessen the burdens of government, while activities related to an ACO's contract with a commercial insurance company probably do not lessen the burdens of government.

FOR FURTHER INFORMATION

For further information about Accountable Care Organizations and how Gorman Health Group can help your organization consider one, please contact Bill MacBain (wmacbain@gormanhealthgroup.com) or John Gorman (jgorman@gormanhealthgroup.com).