FINAL MEDICARE SHARED SAVINGS (ACO) PROGRAM

The Centers for Medicare and Medicaid Services (CMS) unveiled the final Medical Shared Savings Program (MSSP) rule on October 20, 2011. On the same day, the following were also released to effectuate the MSSP: (a) the CMS Center for Medicaid and Medicare Innovation (CMMI) notice announcing testing of the Advanced Payment Program for certain ACOs; (b) the CMS and the Office of Inspector General for Health and Human Services (OIG) Interim Final Rule on waivers of fraud and abuse laws for ACOs; (c) the anti-trust agencies, the Department of Justice (DOJ) and the Federal Trade Commission (FTC), final Statement of Antitrust Policy Enforcement Regarding Accountable Care Organizations, and (d) the Internal Revenue Service restated rules for tax-exempt organizations participating in the MSSP through Accountable Care Organizations.

Some commenters have characterized the changes reflected in the final rule as the most dramatic in the history of rulemaking. Even if hyperbole, CMS in the final rule, does seem to have given serious consideration to the more than 1,300 comments, amongst them comments from CAP, it received on the proposed rule as well as feedback at numerous stakeholder calls and meetings. As a result, the final MSSP overall appears to be more flexible, less burdensome, and potentially more financially palatable. This document outlines the key takeaways from the rule as well as its impact on pathology and pathologists.

Regulatory Impact Analysis

As in the proposed rule, CMS still indicates “there is substantial uncertainty as to the number of ACOs that will participate in the program, their characteristics, provider and supplier response to the financial incentives offered by the Program, and the ultimate effectiveness of the changes in care delivery that may result as ACOs work to improve the quality and efficiency of patient care.” Regardless, it estimates that more organizations, 50 – 270, potentially will become ACOs under the final MSSP than the proposed rule estimated at 75 – 150 ACOs. Correspondingly, CMS estimates a higher potential number of beneficiaries aligned with ACOs or 1 – 5 million rather than 1.5 – 4 million under the proposed rule. The median estimate of MSSP net savings for the program’s initial three-year term is $470 million which is somewhat less than under the proposed rule. CMS validated annual operating costs in the proposed rule and they remain within the same range in the final rule or an average of $1.27 million.

With respect to start-up costs, CMS indicates in the final rule it has “revised many of the policies in the proposed rule, so as to allow for greater flexibility regarding the specific structure and requirements of an ACO and we believe these changes will substantially reduce the burden associated with the infrastructure start-up and ongoing annual operating costs for participation ACOs in the Shared Savings Program.” CMS therefore estimates an average of $0.58 million for start-up investment costs.

CMS estimates total median ACO bonus payments of $1.31 billion during contract years 2012 through 2015. With aggregate average start-up investment costs and ongoing annual operating costs of $451 million, CMS notes a benefit-cost ratio of 2.9 for the program.
In its assessment of the impact on small entities, CMS acknowledges that approximately 95% of physicians are small entities by its definition. CMS does not disregard that the MSSP will affect many small entities, but indicates it drafted the rules and regulations accordingly “in order to minimize costs and burden on such entities as well as maximize their opportunity to participate.” It also stresses that the MSSP is a voluntary program and that payments for individual items and services will still be on a fee-for-service basis.

KEY CHANGES IN THE FINAL RULE

Two Start Dates

As its first sign of flexibility, CMS offers two start dates for ACO participation, April 1, 2012 and July 1, 2012. Although questionable whether the additional three months will accomplish the stated objective, CMS indicates the delayed start date provides an “on ramp” for all ACOs to get appropriate health information exchange in place before entering the program. Initial agreements between CMS and ACOs will run through the end of 2015.

Submission and notification dates by agreement start date are below.

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<tr>
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<th>4/1/2012 Start</th>
<th>7/1/2012 Start</th>
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<tr>
<td>Notice of Intent*</td>
<td>1/6/2012</td>
<td>2/17/2012</td>
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<td>Advanced Payment Program Application</td>
<td>1/3 – 2/1/2012</td>
<td>3/1 – 3/30/2012</td>
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<tr>
<td>CMS notification of approval or denial or application</td>
<td>3/16/2012</td>
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*non-binding

Shared Savings Models – True One Sided Model Adopted

Probably the most significant revision in the final rule and the basis for CMS’s estimates that more ACOs will participate in the MSSP is the creation of a truly one-sided shared savings model. Under the proposed rule, ACOs enrolled in the one-sided model shared in any savings in years one and two. In year three, though, these ACOs were responsible for a portion of any losses they generated beyond a benchmark expenditure. In the final rule, the one-sided option remains a true shared savings model for all three years with ACOs assuming no responsibility for re-payment of any losses. CMS continues to offer the two-sided model under which providers are eligible to share in a greater percentage of savings, but are also responsible for losses from day one. Not surprisingly, CMS expects that more ACOs will choose to enroll in the one-sided model. The one-sided model, though, is only available during the ACO’s initial agreement period with CMS. After the initial agreement period, CMS will not permit ACOs to continue under this model.

As with the proposed rule, ACOs are only eligible for shared savings payments if they meet quality performance standards. CMS eased the requirement somewhat in the final rule so that ACOs are required to achieve the quality performance standard on at least 75% of the measures in each domain rather than 100% to be eligible for shared savings payments.
Under the proposed rule, once ACOs met the required quality measures, their actual expenditures had to be less than the expenditure benchmark based on Medicare fee-for-service expenditures by more than the minimum savings rate plus 2% in order to receive shared savings payments. Under the final rule, CMS has eliminated the additional 2% so that sharing now occurs at the “first dollar” saved. Since the one-sided model no longer includes responsibility for re-payment of any losses, CMS has also removed the 25% withholding.

ACOs may still share in up to 50% of the savings in the one-sided model and 60% of the savings in the two-sided model. CMS increased the performance payment limit in the proposed rule from a cap of 7.5% of benchmark expenditures under the proposed rule to 10% for the one-sided model and from 10% to 15% for the two-sided model thereby enabling high performing ACOs to achieve higher shared savings payments.

With the revised start dates, the first performance period will be 21 and 18 months for the April 1 and July 1 start dates respectively rather than 12 months under the proposed rule. To temper the longer initial performance period, ACOs applying with start dates of April 1 and July 1, 2012 may request an interim calculation and payment based on their financial performance in the first 12 months of their participation. These ACOs must request this calculation at the time of application and must provide documentation of their ability to re-pay any losses arising under the final initial performance period reconciliation.

CMS has also reduced the claims run out period that would drive timing of savings calculations from six months to three months in the final rule. CMS found that applying a three month run out, 98.5% of claims for physician services are complete and 98% of claims for hospital services whereas the completion rate was only 1% higher applying a six month run out period.

Reduction in Quality Measures

The second major revision in the final rule was the reduction from 65 quality measures spanning five domains to 33 measures over four domains.

CMS indicated it selected final measures with a predominantly ambulatory care focus consistent with the primary care focus and beneficiary attribution approach for the MSSP. In fact, CMS removed hospital patient safety measures from the final measures set. CMS also indicated it reduced the number of initial measures based on feasibility, impact, program goals and specific comments received on the proposed rule. CMS sought to include process, outcome and patient experience of care measures.

CMS’s major revision in the final rule on patient experience of care is that in 2012 and 2013, CMS will pay to administer the patient experience surveys, the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey. In 2014, ACOs must select an approved survey vendor to administer the survey and report results to CMS. Of the 33 measures, CMS will collect seven by patient survey, three from claims data, one from electronic health records (EHR) incentive program data, and 22 from the Group Practice Reporting Option (GPRO) web interface under the Physician Quality Reporting System. Note that ACOs must submit quality data on GPRO quality measures.

CMS also revised its quality measure phase-in plan. Year one remains “pay for reporting” meaning that ACOs are required to report on the 33 measures only for purposes of informing quality benchmarks. ACOs that provide accurate and complete reporting on the 33 measures in year one have met the quality performance standard. CMS will not begin using reported data to evaluate ACO performance.

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until years two and three. In year two, CMS will use 25 of the 33 measures for pay for performance calculations and eight will continue to be pay for reporting. In year three, 32 are pay for performance and one for reporting.

In the final rule, CMS eliminated the proposal that as of year two of the ACO agreement at least 50% of an ACO’s primary care physicians (PCPs) be required to be meaningful users of EHRs. EHR adoption is no longer a condition of participation in the MSSP, but is a double-weighted quality measure.

CMS indicates that it anticipates a relatively static set of quality measures for the first agreement period, but also makes clear that measures may change during the course of the MSSP and ACOs would be required to comply with such changes.

**Beneficiary Attribution – Step-Wise Alignment/Preliminary Prospective Assignment with Retrospective Reconciliation**

Having received much objection to its proposed retrospective assignment of Medicare beneficiaries to ACOs, CMS in the final rule, moved from retrospective assignment to preliminary prospective assignment with retrospective reconciliation. It also adopted step-wise alignment. Both of these revisions are described below.

**Step-Wise Attribution**

CMS will still align Medicare beneficiaries with ACOs based on where they received the plurality of primary care services. Instead of the one step alignment under the proposed rule, CMS will employ a two step or what CMS is referring to as step-wise process. As with the proposed rule, CMS will attribute a beneficiary to the ACO with which the beneficiary’s PCP participates. CMS, though, will not stop there as it would have under the proposed rule. It will undertake a second step if the beneficiary is not seeing a PCP and attribute the beneficiary to the ACO where he or she has received at least one primary care service from an ACO physician of any specialty.

**Preliminary Prospective Assignment with Retrospective Reconciliation**

Under this approach, CMS will create a list of beneficiaries likely to receive care from the ACO based on primary care utilization during the most recent periods for which adequate data are available and provide a list of those beneficiaries to the ACO. Unlike the proposed rule, CMS will update the list periodically on a rolling basis throughout the performance year to apprise the ACO of changes in beneficiaries aligned with the ACO. At the end of the performance year, CMS will reconcile the list to reflect the beneficiaries who actually meet the criteria for alignment with the ACO during the performance year. CMS will base its determinations of shared savings or losses on this final reconciled population.

Upon an ACO’s signing participation and data use agreements with CMS, CMS will provide the ACO with a list of preliminary prospectively assigned beneficiaries. In another revision in the final rule, if the ACO has notified beneficiaries using this list and the beneficiaries after 30 days have not declined data sharing, beneficiary affirmative opt-out from sharing their information with the ACO is no longer required. Under the proposed rule, this interaction between ACO and beneficiary regarding opt-out would have occurred at the point of care.

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Composition/Governance

CMS handled the matters of ACO composition and governance in the following fashion in the final rule:

Composition

CMS reiterated it does not believe it should be prescriptive in the number, type and location of ACO participants. CMS found it highly desirable for federally qualified health centers (FQHCs) and rural health centers (RHCs) not only to participate with ACOs, but also to have beneficiaries attributed to them. As such, in the final rule, CMS permitted both FQHCs and RHCs to participate independently as ACOs. Under the proposed rule, FQHCs and RHCs could participate in the MSSP, but only as participants of an ACO rather than on their own.

Amongst the few specifications related to composition, ACO participants who bill Medicare for services rendered by primary care physicians must participate exclusively with a single ACO under the MSSP.

Governance

CMS did not finalize its proposal that each ACO participant have proportionate control of the ACO governing body. It also did not require specific categories of providers or other stakeholders on the governing body, but did retain its requirements that the board (a) is 75% controlled by ACO participants so that the board remains provider-driven and (b) includes a beneficiary. These were absolute requirements under the proposed rule. Under the final rule, if for some valid reason, the ACO is not able to meet the 75% or beneficiary requirements, CMS will not automatically disqualify the ACO’s application. The applicant instead must explain how it will involve ACO participants and beneficiaries meaningfully in ACO governance.

Due to expense and the value CMS ascribes to having an ACO senior level medical director practicing in the community in which the ACO operates, the ACO medical director is no longer required to work full time with the ACO. The senior level medical director still must be a physician, physically present on a regular basis and licensed in the state in which the ACO operates. A separate physician-led quality assurance and clinical process improvement committee is no longer formally required. ACOs, though, still must detail their quality assurance and improvement plans in their application to CMS.

Management of Significant ACO Changes

This was the most commented upon topic in the proposed rule. Under the proposed rule, ACOs could not add or subtract providers during the agreement term. Under the final rule, though, ACOs can add and subtract providers, but must provide 30 days notice to CMS.

Marketing Requirements

ACOs still must submit all marketing materials to CMS. Instead of requiring affirmative approval for all materials as under the proposed rule, the final rule adopts a more simplified, “file and use” approach. If CMS does not disapprove the materials within five business days of submission, they may be used. CMS, however, reserves the right to discontinue use at any time.
ADVANCED PAYMENT PROGRAM

CMMI developed this program based on responses to its solicitation of comments on the concept of advancing payments to certain ACOs that CMS would recoup from their shared savings payments. Eligible organizations are those ACOs that enter the MSSP in April or July 2012 and (1) have less than $50 million in total annual revenue and no inpatient facilities, or (2) have less than $80 million in total annual revenue and whose inpatient facilities are critical access hospitals and/or Medicare low-volume rural hospitals.

CMMI will issue advanced payments to these smaller and/or rural ACOs in the following three forms: (1) up-front fixed payment, (2) up-front variable payment based on the number of historically assigned beneficiaries, and (3) monthly payment varying depending on ACO size. CMMI designed the program to test whether providing an advance will increase participation in the MSSP and allow ACOs to improve care and generate Medicare savings more expeditiously.

ANTITRUST ENFORCEMENT POLICY

Although the FTC and the Antitrust Division of the DOJ received far fewer comments at 127, on their proposed ACO Antitrust Policy Statement than CMS did on its proposed rule, they seem to have taken many of the criticisms and recommendations contained in those comments equally seriously and made some important changes to the proposed statement. Most notably, they removed the requirement that ACOs whose participants have a primary service area (PSA) market share for any common service greater than 50% undergo mandatory antitrust review and receive a favorable response before being eligible to participate in the MSSP.

Under the final statement, “newly formed” ACOs (those that as of March 23, 2010, the enactment date of health care reform legislation, had not yet signed or jointly negotiated any contracts with private payers) may request an antitrust review letter the agencies will provide within 90 days. CMS, though, will not condition participation in the MSSP on a favorable review letter as was the case under the proposed statement. ACOs that are not “newly formed” are not afforded the same option. In fact, the proposed statement did not even apply to such entities. The final statement does apply to all ACOs that are collaborations rather than mergers or single, fully integrated entities regardless of formation date.

The agencies retained the safety zone for arrangements that are highly unlikely to raise significant competitive concerns. As with the proposed rule, for an ACO to be in the safety zone, individual ACO participants that provide the same service must have a combined share of 30% or less in their PSA. Any hospitals and ambulatory surgery centers must be non-exclusive to the ACO for the ACO to fall within the safety zone. The agencies also retained the rural and dominant provider exceptions. The rural provider exception applies to ACOs whose participants may exceed the 30% common service share in their PSA as long as participants are non-exclusive to the ACO. The dominant provider exception applies to those ACOs where common services exceed 50% if no other participant provides the same service in that PSA and the participant is a non-exclusive to the ACO.

As under the proposed statement, the agencies will extend rule of reason analysis to arrangements that have qualified under the MSSP to operate in the commercial market as long as the ACO is using the same governance and leadership structure and clinical and administrative process as it does under the MSSP.

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Finally, under a revision to the final rule, CMS will share with the agencies ACO applications of newly formed ACOs and other data including claims data containing allowed charges and fee-for-service payments for all ACOs to the agencies to aid them in monitoring the competitive effects of ACOs.

**CMS/OIG WAIVER DESIGNS – FRAUD AND ABUSE LAWS**

On the same day CMS released the proposed rule at the end of March, OIG and CMS provided notice and requested comments on waiver designs. As promised, concurrent with the release of the final rule, the agencies released an interim final rule describing five separate fraud and abuse waivers.

By way of reminder, health care reform legislation granted the Health and Human Services Secretary the authority to waive certain fraud and abuse laws (self-referral, anti-kickback, and gainsharing civil monetary penalty (CMP) laws) for purposes of carrying out the MSSP. The gainsharing CMP law addresses hospital payments to physicians to reduce or limit services. The intent of the waiver authority was to avoid inhibiting ACO formation or operation that could occur under the aforementioned laws.

Consistent with the government’s handling of the final ACO rule and the antitrust statement, CMS and OIG gave serious consideration to comments on the waiver designs and made changes to reflect input they received. Largely due to comments expressing concern the proposed waiver designs did not foster ACO development, the waivers under the interim final rule are far broader and much less prescriptive. In addition to the two waivers that the agencies initially proposed and modified under the interim final rule, the agencies introduced three new waivers. The waivers under the interim final rule are still not case-by-case, but applied uniformly to all ACOs and are self-implementing.

The waivers under the interim final rule are as follows:

1. **ACO Pre-Participation Waiver** – applies to “start-up arrangements” employed to develop the ACO prior to the effective date of the ACO’s MSSP agreement with CMS. Certain criteria including documentation and disclosure of the arrangement and a determination by the ACO governing body that the arrangement is “reasonably related”* to the purposes of the MSSP must be fulfilled.

2. **ACO Participation Waiver** – is a blanket waiver for all arrangements between ACOs and their participants to the extent ACOs meet certain criteria most of which resemble those of the pre-participation waiver. This waiver begins as of the effective date of the MSSP agreement and ends the earlier of six months after the agreement expires or the ACO voluntarily terminates. In the event CMS terminates the agreement, the waiver ends on the date of the termination notice.

3. **Shared Savings Distribution Waiver** – applies to distributions of or use of shared savings earned by an ACO subject to certain criteria again including reasonable relationship to the MSSP purposes. Specifically regarding the gainsharing CMP law, any shared savings distributions from hospital must not be intended to induce a physician to reduce or limit medically necessary services. As gainsharing CMP law typically looks at whether payments are intended to reduce or limit services without regard to medical necessity, the agencies clarify they will interpret medical necessity “consistent with the Medicare program rules and accepted standards of practice.”

4. **Compliance with Self-referral Law Waiver** – operates as a waiver of the anti-kickback statute and gainsharing CMP laws for those arrangements that implicate the Stark law and comply with

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an existing exception if the ACO has a participation agreement with CMS and the arrangement is once again reasonably related to the purposes of the MSSP.

5) **Waiver from Patient Incentives** – applies to all beneficiaries, not just those assigned to the ACO under the MSSP, and waives the beneficiary inducement CMP and the anti-kickback statute on certain items and services provided by an ACO or its participants to beneficiaries for free or below fair market value. By way of illustration, CMS and OIG indicate that a blood pressure cuff for a patient with hypertension would be permissible under the waiver, but not theater tickets or beauty products. The waiver does not include waivers of co-payment or deductibles.

*This language replaces "necessary for and directly related to ACO purposes" from the initial waiver designs.

**These waivers are modifications of those in the previous proposed waiver designs. The others are entirely new under the interim final rule.

Although the waivers are definitely broader, the agencies acknowledged some commenters expressed concern that the continued use of fee-for-service payments in the MSSP created an incentive for overutilization. They also indicated they "intend to monitor the program closely for fraud and abuse" and may narrow the waivers to the extent they are negatively impacting the program and/or Medicare funding. Amongst the protections in place, as part of the application process, CMS will screen applicants for a history of program integrity issues and may deny participation based upon such history. ACOs, in their contracts with CMS, must also agree and require their participants to comply with all applicable laws expressly including, but not limited to the anti-kickback statute, civil monetary penalties laws and the physician self-referral law.

Similarly, CMS may immediately terminate an ACO’s participation agreement for violation of the aforementioned laws when no relevant waiver applies. CMS also finalized the requirement that prohibits ACOs and their participants from conditioning participation in the ACO on referrals of federal health care business for those not assigned to the ACO. Another safeguard included in the waivers is the agencies’ transparency requirement mentioned above under which ACOs must publicly disclose such as by website posting the arrangement for which they desire waiver protection.

**IMPACT ON PATHOLOGISTS**

The impact of the final MSSP on pathologists is not dramatically different than it was under the proposed rule. As with the proposed rule, the final rule does not seem to facilitate nor impede pathologists from contributing to ACOs. Like most other specialties other than primary care, the final rule does not really include pathology-specific issues or provisions. The rule’s substantive improvements overall, even if not many are of direct impact on pathologists, are favorable and likely to spur ACO development and expand the breadth of the MSSP from what it would have been under the proposed rule. Observations about changes to certain key areas are below:

**Shared Savings**

That CMS has offered up a truly one-sided model, raised the cap on certain shared savings earnings limits, and announced an advanced payment program is very likely to attract more ACOs to the program. In the very near future, CMMI will announce the 30 or so applicants it selected to participate in its five year Pioneer ACO program for those organizations that already have experience coordinating
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care across settings to test a more rapid transition from traditional fee-for-service to payments for coordination and outcomes. With the selection of roughly 30 Pioneer ACOs and at the top end of the range, an estimated 270 MSSP ACOs, 300 or so ACOs around the country could shortly be under contract with the government. At the same time, coordinated care in the private sector continues to escalate at a consistent and rapid pace. Virtually every major payer has programs in place and announcements of new coordinated care agreements in this arena occur almost daily.

With underlying reimbursement under the MSSP at fee-for-service, a truly one-sided model available with no responsibility for any losses generated under the program, and provider participation completely voluntary, non-participation financially means loss of potential shared savings payments made on top of existing Medicare fee-for-service payments. In the worst case, it also could result in loss in volume and/or revenue if and when referrals for pathology services shift to those pathologists who are ACO participants.

Under the two-sided model, the ACO is responsible for any losses generated from the date of participation which carries with it some risk for the ACO’s participants. It also carries with it the potential for higher incentive payments in addition to base fee-for-service payments as the level of shared savings for which the ACO is eligible from CMS is higher than under the one-sided model.

CMS continues to believe it does not have the authority to mandate how shared savings are distributed. ACOs, though, in their applications must describe how they plan to use shared savings payments, including the criteria they plan to employ for distribution of shared savings amongst ACO participants. As with the proposed rule, incentive payments to individual ACO participants will be a matter of local negotiation and timing. Timing may be of even greater consequence now that the final rule has come to fruition with firm start dates and impending application dates with applications that require inclusion of plans for distribution of shared savings payments.

Quality Measurement

The reduction from 65 proposed measures to 33 with a phase-in period for performance measurement purposes and also from 100% to 70% of all measures in each domain required for shared savings distribution is favorable at both the level of the ACO and individual participants. While none of the adopted 33 measures apply specifically to pathologists, many are still heavily dependent on laboratory data necessitating ACO dependence on laboratories for this data to achieve their performance measures.

The elimination of the requirement that 50% of ACO PCPs be meaningful users of EHR by year two of the agreement and replacement with a double-weighted quality measure is not of much direct impact on pathologists. It may be a favorable indirect move as it creates more distance between ACO operations and meaningful use under which none of the stage one meaningful use objectives and systems requirements are within the pathologists’ usual scope of practice.

The existence of measures in the final rule does not preclude pathologists from presenting to the ACO measures that more effectively demonstrate their data aggregation capabilities and value on population health and care teams or the ACO from rewarding pathologists for such activities. In fact, certain CAP members have been successful in not only presenting these capabilities to their collaborative care leadership, but also in some instances of having measures and incentives based thereupon implemented. CMS’s provision of an updated list of attributed beneficiaries on a rolling basis throughout the performance year under the final rule’s preliminary prospective assignment with

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Interim Final Rule on Fraud and Abuse Law Waivers

While acknowledging the concerns of some commenters about potential overutilization, in order not to impede ACO formation and operation, OIG and CMS went significantly broader in the interim final rule than the proposed waiver designs. This will increase reliance on front end screening of ACO applications and program monitoring for fraud and abuse. The agencies have not closed the door, though, to revision, and foreshadow narrowing the waivers in the event of increased cost or negative effects on patients. In the meantime, much is left to the theoretical concept that ACOs should reduce or eliminate the perverse incentives the self-referral, anti-kickback, and CMP laws seek to prohibit and whether ACO’s referral patterns in practice prove this theory remains to be seen.

Of note, the agencies had entertained extending the safe harbor for electronic health records donations under the anti-kickback statute beyond its scheduled sunset in 2013, but did not expressly adopt this extension. The College has long advocated against the inclusion of laboratories as protected donors under the safe harbor for many reasons including the increasingly wide divergence between current laboratory EHR donation requests and practices and those intended under the safe harbor.