Leaders Looking to Ease Burden on ACOs

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Section 3022 of the Patient Protection and Affordable Care Act (PPACA) mandates the creation of a Medicare Shared Savings Program to be implemented by January 1, 2012. Under the Program, qualified groups of health care providers and suppliers can cooperatively coordinate and manage patient care through the development of an Accountable Care Organization (ACO). ACOs that meet certain criteria and meet quality performance standards are eligible to receive payments for savings created by the ACO.

Many providers are eager to take steps towards the creation of ACOs. However, existing laws and regulatory guidance were not enacted with the ACO model in mind. Specifically, providers must remain cognizant of the Antitrust, Stark, Anti-Kickback and the Civil Monetary Penalties requirements when collaborating with other providers and developing qualifying ACOs.

Representatives of the Centers for Medicare and Medicaid Services (CMS), the Federal Trade Commission (FTC) and the Office of the Inspector General (OIG) recently held a public workshop to discuss these regulatory tensions and possible solutions.

CMS, FTC and OIG leaders expressed a commitment to working cooperatively to interpret and enforce existing guidance and to develop new guidance as necessary so as to encourage innovation while continuing to guard against abuse. However, throughout the workshop, regulatory leaders and panelists continued to struggle with how to navigate the existing legal framework and provide increased guidance and certainty in developing ACOs with the recognition that too much specificity will result in inflexibility, which in turn will hamper the experimentation likely necessary for ACO success. The workshop ultimately revealed very few clear answers as to how regulators intend to address these issues, and providers should stay tuned for new developments and guidance over the next year.

Antitrust Laws

Antitrust laws and regulatory guidance currently in effect may potentially act as a barrier to a provider's ability to coordinate and integrate care through ACOs. Generally speaking, antitrust laws prohibit independent providers from collaborating to engage in anti-competitive activities. However, under existing guidance, the FTC has established safe harbors for certain provider networks. If the network falls within an established safe harbor, the FTC, absent extraordinary circumstances, will not challenge the network on antitrust grounds.

However, the current antitrust framework presents several areas of concern for providers interested in establishing an ACO. For example, the current FTC safe harbors differentiate between those networks that are exclusive versus those that are non-exclusive and favor non-exclusive networks. However, several panelists during the workshop expressed concern regarding this differentiation, as exclusivity may prove to be necessary or even desirable in the ACO context. Similarly, other panelists criticized the current safe harbors generally as creating an impediment to development by focusing on an arbitrary dividing line rather than looking at more relevant, but variable, factors.

In addition, while the creation of any ACO that entails integration among different providers or provider groups would be subject to antitrust scrutiny, the creation of an ACO by a single entity, i.e. by a hospital and its employed physicians, is not currently subject to antitrust oversight. As such, many panelists opined that current antitrust laws will discourage individual providers or provider groups in certain market groups from entering into an ACO arrangement, thus effectively squeezing them out of the market in the area.

Panelists discussed various ways to address these concerns, including the creation of new safe harbors targeted towards ACOs and the establishment of an expedited review process for those ACOs that do not fall within a defined safe harbor. Others suggested that the FTC should merely consolidate and clarify existing scattered guidance regarding health care networks.

<u>Fraud and Abuse Laws</u>

A second potential regulatory barrier to the development of ACOs are the fraud and abuse laws, including the Stark, Anti-Kickback, and Civil Monetary Penalties laws. Generally speaking, these laws are designed to limit or structure financial relationships or payments between referring parties so as to ensure that a provider's medical decision making is not impermissibly influenced by the prospect of financial gain.

However, as above, the current fraud and abuse exceptions and safe harbors are likely ill-suited to the wide array of ACO models that may develop under the Shared Savings Program. As discussed above, regulatory leaders have expressed a clear desire to encourage experimentation and innovation in the development of ACOs. Providers are being encouraged to "think outside of the box" and develop new models of health care delivery that will provide better, more cost-effective care. This kind of innovation is simply not possible under the current fraud and abuse regime.

Panelists discussed two main ways to address this problem during the workshop. First, participants discussed whether new exceptions and safe harbors should be developed which will protect certain likely ACO models. However, many expressed concerns that this will only further heighten the problem, as this will essentially again dictate and constrain the structure that an ACO may permissibly take.

Second, panelists discussed whether and to what extent CMS should utilize the waiver authority granted to it under Section 3022 of PPACA. In its mandate to create the Shared Savings Program, PPACA also granted the Secretary to waive the requirements of the Stark, Anti-Kickback, and Civil Monetary Penalties laws. Some panelists argued that waivers should not be utilized at all, and that regulators should instead rely on revised or newly created exceptions and safe harbors. Other panelists at the other end of the spectrum advocated for a blanket waiver which would apply to any and all models of ACOs.

<u>Conclusion</u>

Although the workshop provided no clear answers, it did reflect the governmental agencies' awareness of the hurdles to ACO development and a commitment to provide guidance to the industry.

Although additional guidance is expected in the upcoming months, including the Shared Savings Program regulations, providers cannot afford to wait until all issues have been definitively resolved. Providers should begin considering potential ACO options that substantially comply with existing regulations and further the goals of increasing quality care and reducing costs to the Medicare program. For assistance with ACO formation or participation, please contact Amy K. Fehn, Esq. or Laura C. Range, Esq. at 248-544-0888.