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Strategic growth requires a proactive and agile process for managing organizational conflicts of interest ("OCIs"), avoiding them where possible and mitigating them where necessary. Nowhere is this more true than contracting with the Centers for Medicare & Medicaid Services ("CMS") to support the Medicare Program. CMS relies on an alphabet soup of contractors to administer the Medicare Program, including the MACs that process claims in the first instance; the RACs and UPICs that perform further post-payment review to identify improper payments and/or fraud, waste, and abuse; and the Qualified Independent Contractors ("QICs") that handle appeals from claims decisions, just to name a few. Every year, CMS's contractors make expert decisions that affect the payment of more than $645 billion from the Medicare Trust. CMS reasonably insists that those contractors be free from any unmitigated OCIs that could impair their decision-making.

EMPHASIS ON IMPAIRED OBJECTIVITY

FAR 2.101 generally defines the term "OCI" as a situation in which, because of other activities or relationships, a company is unable to provide impartial assistance or advice to the Government, a company's objectivity in performing contract work is otherwise impaired, or a company has gained an unfair competitive advantage. Although FAR Subpart 9.5 provides general guidance for identifying and resolving OCIs, most contractors attempt to analyze OCIs using the three categories identified in bid protest caselaw:

- Unequal access to information. This scenario occurs when, by virtue of its performance of a Government contract, a contractor is exposed to certain nonpublic information that provides the contractor with an unfair competitive advantage on a future procurement.

- Biased ground rules. This scenario occurs when a government contractor is involved in setting the rules for a procurement, e.g., developing technical specifications or work statements or creating evaluation criteria. In these circumstances, the contractor would have an unfair competitive advantage if it were permitted to compete for the contract based on those rules or requirements that it helped develop.

- Impaired objectivity. This scenario occurs when a contractor's work for the Government could involve evaluating itself, an affiliate, or a company in which it has a financial interest, through an assessment of performance under another contract or through the evaluation of proposals. In these circumstances, the Government is concerned about the contractor's ability to render impartial advice.

Because the work of Medicare contractors is so critically important to the proper payment of money from the Medicare Trust, "impaired objectivity" OCIs present the greatest challenge. Nowhere is this emphasis more visible than in the OCI clauses that CMS includes in Medicare contracts. CMS has developed a standard OCI clause with variations for different contracting programs. CMS's OCI clause contains many notable features, including:

- A general, non-exclusive listing of entities for which an OCI would exist if the contractor had a financial interest or relationship with any of the entities;

- A broad definition of "financial interest/relationship" that encompasses virtually any arrangement involving "compensation" and applies to both "direct or indirect relationships including, but not limited to, the Contractor and its parent company, subsidiaries, affiliates, subcontractors, clients and principals";

- For certain contractors, a proposed restriction on holding other Medicare contracts (e.g., a MAC generally cannot be a RAC in the same jurisdiction);

- Extensive disclosure and certification requirements, including a requirement to update the disclosure and certification at least annually; and

- A requirement that the contractor undergo an independent audit of its OCI program.

BE PROACTIVE: IT'S AN OCI IF THE CONTRACTING OFFICER SAYS ITS AN OCI

The FAR, caselaw, and CMS's OCI clause give contracting officers wide discretion in determining whether a particular opportunity gives rise to an OCI and whether that OCI can be avoided or mitigated. The process of identifying and resolving potential OCIs is both procurement-specific and fact intensive, making it difficult for both the Government and contractors to develop bright line tests applicable in all situations. Although general guidelines can be developed for categories of services and customers, these guidelines cannot be considered definitive for every procurement that may fall within those categories. Contractors would do well to approach OCIs with the following rule of thumb: It's an OCI if the contracting officer says it's an OCI, and the OCI is mitigated if the contracting officer says it's mitigated.

Approaching OCI's in this manner requires contractors to be proactive. Managing OCIs is a time-consuming process that requires extensive coordination among business development, operations, legal, and compliance personnel. Contractors should endeavor to identify potential OCIs as early as possible in the business development cycle, and well before a final bid/no-bid determination is made. Early identification of OCIs permits proactive outreach to CMS, which, in turn, provides the contractor with a chance to frame a potential financial interest or relationship in the best light. Early identification also avoids wasted business development effort on opportunities that CMS will not accept.

KEY CONSIDERATIONS

Although there are few bright line OCI tests, there are a number of factors that contractors should consider in identifying and resolving OCIs:

- Importantly, the FAR does not require that every OCI be avoided, mitigated, or neutralized. Instead, FAR 9.504(a) requires that contracting officers "[a]void, neutralize, or mitigate *significant* potential conflicts before contract award." Accordingly, when framing a potential issue to CMS, the best strategy often is to make the case that any conflict is remote and/or insignificant and therefore need not be mitigated. Mitigation can and should be offered as part of a "belt and suspenders" approach, but jumping straight to mitigation may miss an opportunity to effectively manage an OCI.

- Make the case that allowing your company to maintain the potentially conflicting interest or relationship is in the best interest of CMS and the Medicare Program. CMS demands innovation from its Medicare contractors, and innovation is particularly important given the dynamic healthcare industry. Oftentimes, a potential conflict can also be framed as an efficiency, economy of scale, or an opportunity to leverage the technology and expertise of another participant or area of the healthcare industry. These considerations may influence whether CMS finds an OCI in the first instance, and they will certainly influence whether CMS considers a waiver under FAR 9.503.

- A primary concern of CMS is financial relationships with healthcare providers that submit claims for reimbursement to Medicare. Tread very carefully in this area, and be aware that the integration of providers and payers in the healthcare industry makes it increasingly difficult to distinguish providers from other entities.

- Because most OCIs in the Medicare Program are "impaired objectivity" OCIs, it is very difficult to mitigate them. Again, because only significant OCIs need to be mitigated, contractors should always seek to demonstrate in the first instance that any OCI is de minimis or remote and therefore not significant. However, if CMS does deem an impaired objectivity OCI significant, CMS likely would not consider intra-corporate firewalls to be sufficient mitigation. Other agencies have accepted two methods as viable mitigation strategies for impaired objectivity OCIs: (1) conflict-free subcontractors; and (2) independent verification and validation. However, contracting officers have discretion to accept or reject either of these proposed solutions in any given situation.

- When analyzing potential conflicts with other healthcare programs (TRICARE, the VA health system, Medicaid, etc.), understand the extent to which dual-eligibles are involved and when Medicare pays relative to other payers. For example, CMS historically has not deemed it a conflict for a MAC to provide similar administrative services in support of the TRICARE Program. This makes sense because, for dual-eligible beneficiaries under Medicare and TRICARE, Medicare pays first for Medicare-covered services. Because Medicare has primary liability for covered services, the potential for improper payments by Medicare is reduced.

Finally, the attention necessary to properly manage OCIs can cause contractors to overlook the growing focus on personal conflicts of interest ("PCIs"). Properly managing PCIs requires analysis of different data (individual investments and activities of officers, managers, board members, and key personnel), and the tools for mitigating PCIs are different (e.g., recusal, divestiture, and firewalls often take on greater importance). Contractors that believe they are successfully navigating OCI waters are often surprised to learn how close they have come to the PCI shoals, and some contractors do not realize this danger until it is too late.

Vinson & Elkins has extensive experience counseling and representing contractors supporting the Medicare, TRICARE, VA, and Medicaid programs. Please reach out to Daniel P. Graham or Tyler E. Robinson if you have any questions.

This article is intended for educational and informational purposes only and does not constitute legal advice or services. These materials represent the views of and summaries by the author. They do not necessarily reflect the opinions or views of Vinson & Elkins LLP or of any of its other attorneys or clients.

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A Tale of
Two Epidemics

HEPATITIS C
in Baby Boomers and Young Adults

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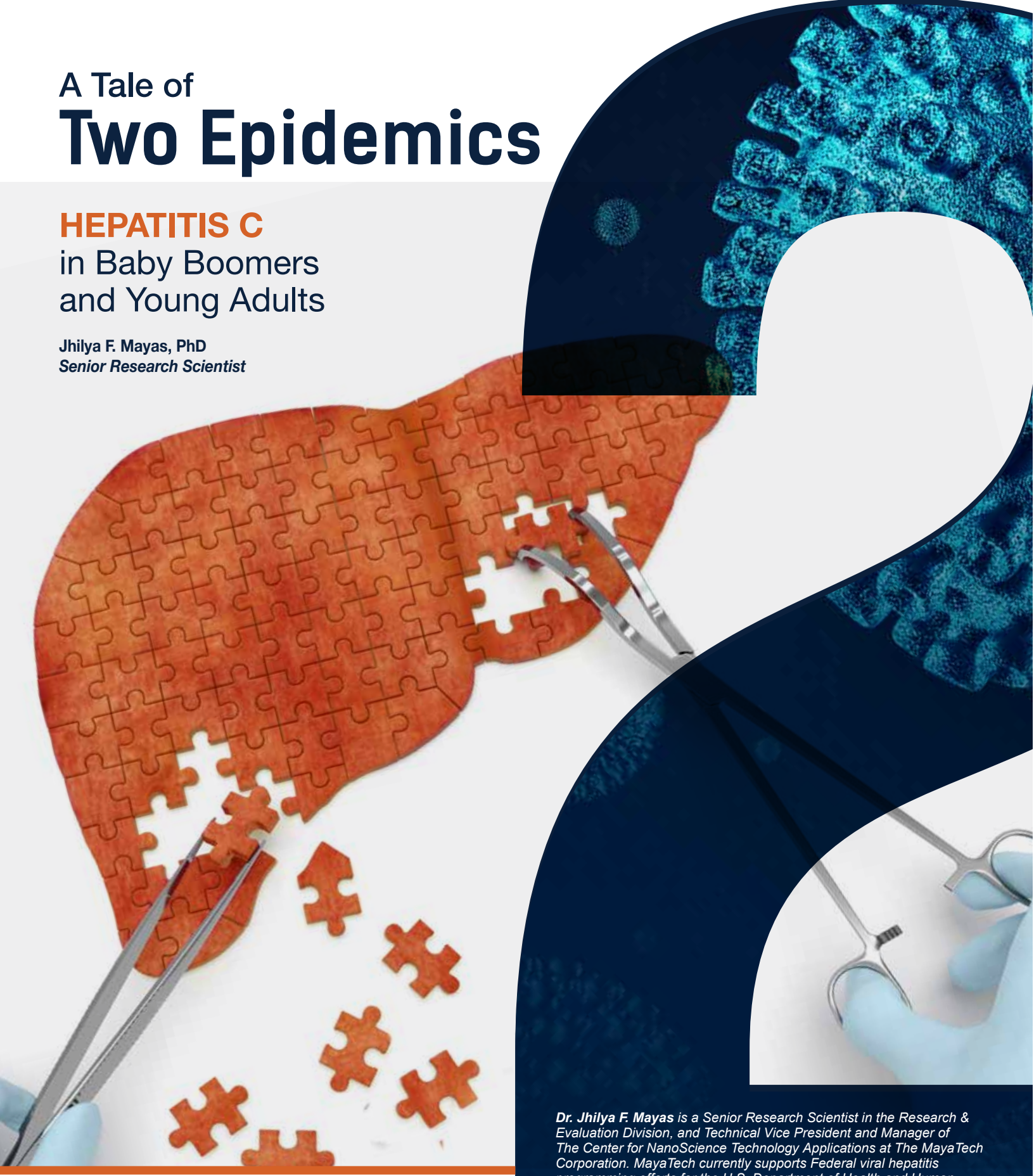

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Hepatitis C infection

is a significant public health concern that impacts an estimated 3.5 million people in the United States.[1] Recent estimates indicate that new infections have increased steadily in the past five years, with a nearly three-fold increase between 2010 and 2015.[2] Hepatitis C infection often presents without symptoms and can progress slowly, causing liver damage over many years or decades. Currently, the efforts to address hepatitis C infection have become two-pronged:

ADDRESSING CHRONIC INFECTION
Focus on age-based screening for Baby Boomers, regardless of risk factors.

ADDRESSING ACUTE (NEW) INFECTION
Focus on preventing and identifying new hepatitis C infections among young injection drug users (particularly associated with the current opioid epidemic).

BABY BOOMER SCREENING

In 2012, the U.S. Centers for Disease Control and Prevention (CDC) recommended that all Baby Boomers, people born between 1945 and 1965, receive a one-time test for hepatitis C – regardless of the presence of any specific risk factor. Risk factors for hepatitis C infection are well documented;[3] however, in at least 20% of diagnosed individuals, the specific risk factor is unknown. The most common route of hepatitis C infection is through injection drug use, and patients often experience stigma from health care providers and their community about any history of drug use. The CDC recommendations describe testing without consideration of additional risk factors, which has encouraged individuals at the greatest risk to request and/or receive testing without having to navigate provider stigma and judgment. These recommendations were based on epidemiological data indicating that approximately 75% of those living with chronic hepatitis C were within the Baby Boomer age cohort. A recent Canadian study suggests that most Baby Boomers were infected during early childhood, likely through inadequate sterilization techniques available at the time.[4] These data provide further support for promoting one-time screening based on age alone.

CDC developed the *Know More Hepatitis* campaign, specifically targeting Baby Boomers with awareness messages promoting hepatitis C testing. Despite multifaceted approaches by Federal and non-Federal entities to promote Baby Boomer testing, including U.S. Preventive Services Task Force (USPSTF) recommendations in 2013, less than 15% of Baby Boomers have ever received a hepatitis C test.[5] Given the strength of the supporting epidemiological data and the unambiguous nature of the Baby Boomer recommendations, more work is needed to motivate both health care providers and Baby Boomers themselves to pursue testing.

YOUNG PEOPLE WHO INJECT DRUGS (PWID)

In 2010, new hepatitis C infections began to rise substantially, concomitant with an increase in injection drug use. The demographic of those newly infected with hepatitis C was overwhelmingly young white adults living in non-urban areas with current injection drug use. The opioid abuse crisis escalating throughout the United States is resulting in an increase in comorbid infectious diseases, including hepatitis C and HIV, such as the 2015 outbreak experienced in Scott County, Indiana and in other areas of the country. The documented trend and stark trajectory in new infections demand a robust public health effort to address a host of factors, including:

- Comprehensive prevention strategies for PWID (e.g., education, syringe services programs, integrated service provision)
- Prevention of perinatal hepatitis C transmission
- Geographical considerations (e.g., rural populations)

Frank discussions about injection drug use and the associated elevated risk of hepatitis C infection are one of many components to arresting and reversing the comorbidities of the opioid epidemic. Destigmatization of injection drug use will continue to be an important component of any hepatitis C intervention. Given the continued rise in new infections, attention must also be paid to young substance users, understanding their unique challenges and motivators, and coordinating where possible, with other services to achieve efficient and effective management.

KEY TAKEAWAYS & LOOKING FORWARD

The steady rise in hepatitis C infections continues to be of great concern, with an estimated 33,900 new infections in 2015.[2] Young adults aged 20-29 had the highest rates of new infection, highlighting a need to strengthen prevention efforts, particularly among PWID. Baby Boomers remain among those with consistently low rates of new infection, yet still bear a disproportionate burden of chronic disease. Public health efforts to address this complex epidemic must consider the high price of curative therapy, suboptimal screening rates, additional needs of target populations (e.g., substance use disorders among young adults, comorbid medical conditions among Baby Boomers), and societal stigma. Additionally, the price of curative hepatitis C treatment remains an issue for both patients and insurers. While there are substantial benefits to curing hepatitis C infections (halting or reversing liver disease, preventing liver cancer, and preventing liver-related death), ongoing controversy around cost efficiencies and patient access to treatment remain as significant barriers to ending the epidemic of hepatitis C in **all** populations.

[1] U.S. Centers for Disease Control and Prevention. Viral Hepatitis Statistics and Surveillance. [2] U.S. Centers for Disease Control and Prevention. Surveillance for Viral Hepatitis – United States, 2015. [3] U.S. Centers for Disease Control and Prevention. Hepatitis C FAQs for Health Professionals. [4] Joy JB, McCloskey RM, Nguyen T, et al. The Spread of Hepatitis C Virus Genotype 1a in North America: A Retrospective Phylogenetic Study. *Lancet Infectious Diseases.* 2016;16(6)698-702. [5] Jemal A, Fedewa SA. Recent Hepatitis C Virus Testing Patterns among Baby Boomers. *American Journal of Preventive Medicine.* 2017;53(1):e31–e33.

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