**December 2020**

Dear Health Law Section Members:

The Health Law Section ("HLS") website has been updated with October through November, 2020 articles on significant developments in the health law arena that may be of interest to you in your practice.

These summaries are presented to HLS members for general information only and do not constitute legal advice from The Florida Bar or the HLS. HLS thanks the following volunteers who have generously donated their time to prepare these summaries for our members:

- **Amy Morse, Esq.,** ***Morse & Morse, LLC***
- **Brian E. Dickerson, Esq., Anthony J. Calamunci, Esq., Nicole Hughes Waid, Esq., Amy Butler, Esq.,** ***FisherBroyles, LLP***
- **Christian Perez Font, Esq.,** ***Thinkeen Legal, P.A.***
- **Gaurav J. Dhiman, J.D. Candidate,** ***University of Miami School of Law***
- **Jamie B. Gelfman, Esq. and Timothy S. Wombles, Esq.,** ***Nelson Mullins Broad and Cassel***

Thank you,

**Jamie B. Gelfman, Esq.,** ***Nelson Mullins Broad and Cassel,*** **HLS Editor in Chief**

**Ashley Brevda, Esq., Corp Counsel/Chief Compliance Officer,** ***Oncology Analytics, Inc.,*** **HLS Team Editor**

**Trish Huie, Esq.,** ***Patricia A. Huie, PLLC,*** **HLS Team Editor**

## TABLE OF CONTENTS

## FRAUD AND ABUSE UPDATES

### Department of Health and Human Services Issues Special Fraud Alert on Live Speaker Programs

On November 12, 2020, the U.S. Department of Health and Human Services, Office of Inspector General ("HHS-OIG") issued a rare Special Fraud Alert (the "Alert").[1] The Alert reinforces the inherent risks of federal Antikickback Statute ("AKS") violations when pharmaceutical or medical device manufacturers sponsor events in which physicians or other healthcare providers make speeches or presentations for which they receive remuneration. Given the pandemic, HHS-OIG also took the opportunity to urge companies to reconsider restarting in-person programs even when the pandemic abates.

Over the course of many years, and to the tune of hundreds of millions of dollars in settlements, many pharmaceutical and medical device manufacturers have been violated the AKS for rewarding speakers with lucrative speaker fees, trips, expensive dinners and other "red-flag" activities like fishing excursions, entertainment at adult venues, sporting events and the like. The speakers themselves are likewise subject to penalties for accepting anything of value, directly or indirectly, from such companies as inducements or rewards for referrals or orders of items or services.

While not all speaking engagements are in violation of the AKS, sponsorship or participation in speaker programs are subject to increased scrutiny by HHS-OIG and the U.S. Department of Justice ("DOJ"), and this includes sponsors, speakers and even attendees who receive something of value (including free food and drinks) that could serve as an inducement to make referral or use a company's drugs or medical devices. The Alert provides a bulleted list of characteristics that, taken together or separately, potentially indicate a program that may violate the AKS. The Alert also notes that the list is illustrative, not exhaustive:

- The company sponsors speaker programs where little or no substantive information is actually presented;
- Alcohol is available or a meal exceeding modest value is provided to the attendees of the program (the concern is heightened when the alcohol is free);
- The program is held at a location that is not conducive to the exchange of educational information (e.g., restaurants or entertainment or sports venues);
- The company sponsors a large number of programs on the same or substantially the same topic or product, especially in situations involving no recent substantive change in relevant information;
- There has been a significant period of time with no new medical or scientific information nor a new FDA-approved or cleared indication for the product;
- Health care professionals ("HCPs") attend programs on the same or substantially the same topics more than once (as either a repeat attendee or as an attendee after being a speaker on the same or substantially the same topic);
- Attendees include individuals who don't have a legitimate business reason to attend the program, including, for example, friends, significant others, or family members of the speaker or HCP attendee; employees or medical professionals who are

members of the speaker's own medical practice; staff of facilities for which the speaker is a medical director; and other individuals with no use for the information;
- The company's sales or marketing business units influence the selection of speakers or the company selects HCP speakers or attendees based on past or expected revenue that the speakers or attendees have or will generate by prescribing or ordering the company's product(s) (e.g., a return on investment analysis is considered in identifying participants);
- The company pays HCP speakers more than fair market value for the speaking service or pays compensation that takes into account the volume or value of past business generated or potential future business generated by the HCPs.

Pharmaceutical and medical device manufacturers should properly interpret the issuance of the Alert as an indicator that despite the pandemic and the lull in in-person events, HHS-OIG and DOJ have no intention of taking their eye off the ball when it comes to AKS enforcement.

**Submitted by:** **Brian E. Dickerson, Esq., Anthony J. Calamunci, Esq., Nicole Hughes Waid, Esq., and Amy L. Butler Esq., *FisherBroyles, LLP***

## FRAUD AND ABUSE UPDATES

### Recent Health Care Fraud Enforcement Actions

On September 30, 2020, the U.S. Department of Justice ("DOJ") announced that with the cooperation of the Federal Bureau of Investigation ("FBI"), Drug Enforcement Agency ("DEA"), Department of Health and Human Services, Office of Inspector General ("HHS-OIG"), and over 40 U.S. Attorney's Offices, 345 individuals in 51 federal districts were charged with filing more than $6 billion in false or fraudulent claims to both federal health care programs and private insurers.[2]

Most of the charges related to telemedicine schemes, confirming the industry's concern that the use of telemedicine during COVID would lead to fraud and abuse. The telemedicine-related charges comprise $4.5 billion of the alleged $6 billion in false and fraudulent claims.[3] The second largest category of charges relate to false and fraudulent claims for treatment and testing of patients seeking care for substance use disorder and behavioral health. The substance use-related charges comprise more than $845 million of alleged false and fraudulent claims for "unnecessary drug testing, billing for treatments not provided, and prescribing unnecessary treatments."[4]

The investigation began in April 2020 and the use of data analytics resulted in enforcement moving faster than ever before in investigations and prosecutions. It is likely the DOJ will continue to use data analytics to identify fraudulent practices.

Also significant, is that some of the substance use disorder charges stem from a violation of the Eliminating Kickbacks in Recovery Act ("EKRA"), which prohibits remuneration in return for referring a patient to a recovery home, clinical treatment facility, or laboratory.[5] EKRA was passed in 2018. Prior to these charges, only one individual was charged with an EKRA violation.

Finally, there were two themes noted in the substance use disorder cases: (1) providers failed to establish a physician/patient relationship because the providers would "cold call" prospective patients, and (2) medical director oversight was insufficient because they served as medical directors for numerous facilities and could not provide the necessary oversight.[6]

**Submitted by:** **Amy Morse, Esq.,** ***Morse & Morse, LLC***

## REGULATORY UPDATES

### Department of Health and Human Services Announces Changes to the Medicare "*Most Favored Nation*" Pricing Rule

On November 20, 2020, the U.S. Department of Health and Human Services ("HHS") announced changes to the Medicare "Most Favored Nation" ("MFN") pricing rule that would extend referential pricing beyond the United States. This action was prompted by an HHS study that found that the prices paid by Medicare for 27 drugs that accounted for 64% of total Medicare Part B drug spending in 2016 were on average 1.8 times higher than in other developed countries. Under the proposed rule, starting in January 2021, HHS will test a new 7-year MFN model that will include referential drug prices in Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Iceland, Ireland, Israel, Italy, Japan, Republic of Korea, Luxembourg, Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland, and the United Kingdom. The pharmaceutical industry has long resisted efforts to expand MFN pricing beyond the United States so it is likely that the rule will receive a significant amount of pushback and challenges.

The full text of the proposed rule is available in the following link: https://innovation.cms.gov/media/document/mfn-ifc-rule and will be open for public comment for sixty days following publication in the Federal Register.

**Submitted by:** **Christian Perez Font, Esq., *Thinkeen Legal, P.A.***

## REGULATORY UPDATES

### OIG Finalizes Coordinated Care Revisions to the Anti-Kickback Statute and Civil Monetary Penalties Law[7]

The United States Department of Health and Human Services' Office of Inspector General ("OIG"), in coordination with the Centers for Medicare & Medicaid Services ("CMS"), issued a Notice of Proposed Rulemaking, "Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Rules Regarding Beneficiary Inducements" (the "Proposed Rule"), on Oct. 9, 2019 which sought to align existing regulations with and remove regulatory impediments to the healthcare industry's shift toward value-based and coordinated care payment models.[8] The Proposed Rule was a component of the Regulatory Sprint to Coordinated Care initiative, launched by HHS in 2018.

After receiving 337 comments from various stakeholders, OIG finalized the new and modified Anti-Kickback Statute ("AKS") safe harbors and exception to the Beneficiary Inducements civil monetary penalty law ("Beneficiary Inducements CMP") as set forth in the Proposed Rule on Nov. 20, 2020, to be effective on Jan. 19, 2021 (the "Final Rule"). In the Final Rule, OIG sets forth protections under the AKS for certain coordinated care and value-based arrangements, as well as protections under the AKS and Beneficiary Inducements CMP regarding incentives offered to beneficiaries to encourage patient engagement that would otherwise be prohibited. A high-level summary of the AKS Safe Harbors and Beneficiary Inducements CMP is provided below.

#### A. Final Modifications to the AKS

The AKS is an intent-based statute that prohibits a person from knowingly and willfully soliciting or receiving, or offering or paying, any remuneration to a person in return for referring, or to induce such person to refer, an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a federal health care program, or for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service or item for which payment may be made in whole or in part under a federal health care program.[9] The AKS regulations carve out various exceptions to the definition of "remuneration," which describe certain payment arrangements that, if all elements are met, would not be construed as violating the AKS (the "Safe Harbors").

The Final Rule sets forth seven additions and four modifications to the Safe Harbors designed to strike a balance between "flexibility for beneficial innovation and better coordinated care with necessary safeguards to protect patients and Federal health care programs," by enabling arrangements that advance coordination and management of patient care; supporting innovative methods and novel arrangements; and broadening the use of digital health technology, such as remote patient monitoring and telehealth. A high-level summary of the Safe Harbor additions and revisions follows. Note that each of these Safe Harbors contains significantly more detail than described here, including a substantial number of new definitions and elements.

### 1. Value-Based Arrangements

OIG adopted three new safe harbors to the AKS for remuneration exchanged between or among eligible participants in a value-based arrangement involving both publicly and privately insured patients with the intent that such arrangements are used to improve quality, outcomes, and efficiency through the use of innovative methods and novel arrangements, including the use of digital health technology, such as remote patient monitoring and telehealth technologies. The greater the financial risk of the parties, the more flexibility offered by these Safe Harbors.

For purposes of these Safe Harbors, OIG finalized the definition of a "value-based arrangement," which is "an arrangement for the provision of at least one value-based activity for a target patient population between or among: (i) the value-based enterprise ("VBE") and one or more of its VBE participants; or (ii) VBE participants in the same value-based enterprise." Such an arrangement must be in writing and be commercially reasonable. OIG defines "VBE" as "the network of individuals and entities that collaborate together to achieve one or more value-based purposes." OIG clarified that only the VBE and its participants (or VBE participants in the same VBE) may be parties to a value-based arrangement and such arrangement does not protect remuneration to the VBE participants' contractors or to beneficiaries. The value-based arrangement may be between as few as two parties or may be among many participants.

The protections offered by the value-based arrangement Safe Harbors are prospective only and will be effective sixty (60) days after the Final Rule is published in the Federal Register.[10]

- **Value-Based Arrangements Safe Harbors (Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency without Requiring the Parties to Assume Risk; Arrangements with Substantial Downside Financial Risk; Arrangements with Full Financial Risk):** The new value-based arrangement Safe Harbors set forth the types of protected remuneration, the types of entities eligible to rely on the Safe Harbors, and the types of safeguards included in the Safe Harbors, which vary depending on the level of financial risk assumed by the parties. While all of the value-based arrangement Safe Harbors offer protection for in-kind remuneration (e.g., technology or services), only the arrangements with substantial downside financial risk and full financial risk offer protection for monetary remuneration (e.g., shared savings or performance bonus payments). Each of the value-based arrangement Safe Harbors is described, in turn, below.

    - **Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency without Requiring the Parties to Assume Risk (42 C.F.R. § 1001.952(ee)):** OIG finalized this Safe Harbor for in-kind remuneration exchanged between qualifying VBE participants that do not assume any risk or assume less than substantial downside risk. The requirements for this Safe Harbor include commercial reasonableness, written documentation, record retention, and the establishment and monitoring of legitimate outcome or process measures that the parties reasonably anticipate will advance the "coordination and management of care for the target patient population based on clinical evidence or credible medical or health science support." The remuneration must be used predominantly to

engage in activities directly connected to the coordination and management of care for the target patient population without resulting in more than incidental benefits to persons outside of the target patient population. The offeror of the remuneration is prohibited from taking into account the volume or value of, or conditioning the remuneration on, "(i) referrals of patients that are not part of the value-based arrangement's target patient population; or (ii) business not covered under the value-based arrangement." The value-based arrangement must not contain restrictions on directing or restricting referrals and may not include marketing items or services to patients or patient recruitment activities. OIG also conditioned this Safe Harbor on the recipient's payment of at least 15% of the offeror's cost for the in-kind remuneration

- **Arrangements with Substantial Downside Financial Risk (42 C.F.R. § 1001.952(ff):** This Safe Harbor covers both in-kind and monetary remuneration and offers greater flexibility than the Care Coordination Safe Harbor. Although the elements of this Safe Harbor are similar to the Care Coordination Safe Harbor, this Safe Harbor also requires that the VBE has assumed substantial downside financial risk from a payor for a period of at least one (1) year. In addition, the remuneration "must be used predominantly to engage in value-based activities that are directly connected to the items and services for which the VBE is at substantial downside financial risk."

- **Arrangements with Full Financial Risk (42 C.F.R. § 1001.952(gg)):** The Full Financial Risk Safe Harbor also covers both in-kind and monetary remuneration. Full financial risk means that "the VBE is financially responsible on a prospective basis for the cost of all items and services covered by the applicable payor for each patient in the target patient population for a term of at least 1 year." This Safe Harbor does not protect an ownership or investment interest in the VBE or any distributions related to an ownership or investment approach. This Safe Harbor requires, among other elements, that the arrangement be set forth in writing, be for a period of at least one (1) year, and not take into account referrals of patients who are not part of the target population or business not covered under the value-based arrangement.

### 2. Additional New AKS Safe Harbors

OIG finalized four additional, new Safe Harbors as set forth in the Proposed Rule, with some slight modifications.

- **Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes and Efficiency (42 C.F.R. § 1001.952(hh)):** This Safe Harbor protects only in-kind remuneration in the form of patient engagement tools and support furnished directly by VBE participants to patients in a target patient population in order to improve quality, health outcomes and efficiency.

- Remuneration permissible under this Safe Harbor include in-kind items, goods, and services. OIG declined to provide specific examples of protected items, goods or services, but clarified that preventive items, goods and services can be protected under this Safe Harbor. Cash and cash equivalents are not protected under the Safe Harbor, although some gift cards may be considered in-kind remuneration eligible for protection if their potential use is limited to certain categories of items or services that meet the conditions of the Safe Harbor, including the requirement that the remuneration have a direct connection to the coordination and management of the care of the target patient population.

- OIG noted that certain entities are ineligible to utilize this Safe Harbor to furnish protected remuneration to patients: pharmaceutical manufacturers, wholesalers, and distributions; pharmacy benefit managers; laboratory companies; pharmacies that primarily compound drugs or primarily dispense compounded drugs; manufacturers of devices or medical supplies (except with respect to digital health technology); entities or individuals that sell or rent DMEPOS (other than a pharmacy, medical device or supply manufacturer that also sells or rents DMEPOs, or a physician, provider or other entity that primarily furnishes services); medical device distributors or wholesalers that are not otherwise manufacturers of devices or medical supplies; and medical device manufacturers, distributors, or wholesalers with ownership or investment interests held by physicians ("Ineligible Entities").

- The patient engagement tool or support must not be funded or contributed by a VBE participant that is not a party to the applicable value-based arrangement or by any of the Ineligible Entities.

- Note that because a practice permissible under the AKS is also excepted from the Beneficiary Inducements CMP, this Safe Harbor would also remove barriers presented by the Beneficiary Inducements CMP.

- **CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives (42 C.F.R. § 1001.952(ii)):** This Safe Harbor is intended to protect remuneration "between and among parties to arrangements (e.g., distribution of capitated payments, shared savings or losses distributions) under a model or other initiative being tested or expanded by the Innovation Center under section 1115A of the Act or under the Medicare Shared Savings Program ('CMS-sponsored models'), as well as to protect remuneration "in the form of incentives provided by CMS-sponsored model participants and their agents under a CMS-sponsored model to patients covered by the CMS-sponsored model."

    - OIG clarified that CMS will determine the specific types of financial arrangements and incentives to which this Safe Harbor applies.

    - The Safe Harbor does not necessarily apply to every possible financial arrangement or incentive that CMS-sponsored model parties may wish to implement pursuant to the Medicare Shared Savings Program or an Innovation Center model.

- The CMS-sponsored model patient incentive must have a direct connection to the patient's health care, unless the participation documentation specifies a different standard.

- The start and end date for protection under this Safe Harbor differs depending on whether the CMS-sponsored model is governed by participation documentation in the form of a legal instrument setting forth the terms and conditions of a grant or a cooperative agreement.

- **Cybersecurity Technology and Services (42 C.F.R. § 1001.952(jj)):** This Safe Harbor, which is intended to protect arrangements intended to address the increasing threat of cyberattacks impacting health care entities, protects donations of software and other types of information technology, as well as certain cybersecurity hardware.

    - Specifically, the Safe Harbor will protect "nonmonetary remuneration (consisting of cybersecurity technology and security that is necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity."

    - This Safe Harbor is intended to ensure consistency with the Electronic Health Records Items and Services Safe Harbor (described in detail below).

    - The Safe Harbor protects all donors and recipients, without any limitations on the type of individual or entity donating or receiving cybersecurity technology and services. Donors and recipients must enter into a written agreement signed by the parties describing the technology and services being provided, but this does not have to be reduced to a single document.

    - There is no monetary limit set forth in the Safe Harbor. However, donations are not protected if donors directly take into account the volume or value of referrals or other business generated between the parties when determining the eligibility of a potential recipient for the technology or services, or the amount or nature of the technology or services to be donated. Further, the donor may not shift the costs of technology or services to any federal health care program.

- **Accountable Care Organizations ("ACO") Beneficiary Incentive Program (42 C.F.R. § 1001.952(kk)):** The Balanced Budget Act of 2018 added sections to the Social Security Act (the "Act") that allow ACOs to apply to operate ACO Beneficiary Incentive Programs, and the Act states that "illegal remuneration" under the AKS does not include incentive payments made to Medicare fee-for-service beneficiaries by an ACO under an ACO Beneficiary Incentive Program. In the Proposed Rule, OIG proposed to codify this statutory exception, clarifying that an ACO may furnish incentive payments only to assigned beneficiaries, so long as the payment is made in accordance with the requirements set forth in Section 1899(m) of the Act. The OIG finalized this Safe Harbor without any modifications.

### 3. Modifications to Existing Safe Harbors

OIG finalized proposed modifications to four existing Safe Harbors:

- **Outcomes-Based Payments and Part-Time Arrangements (42 C.F.R. § 1001.952(d)):** OIG finalized its three significant proposed modifications regarding this Safe Harbor.

    - OIG replaced the requirement that aggregate compensation under these agreements be set in advance with a requirement that the methodology for determining compensation be set in advance. OIG stated that this change modernizes the Safe Harbor and provides for enhanced flexibility to the health care industry to undertake innovative arrangements, including arrangements supporting the transition to value and better coordinated care for patients.

    - OIG eliminated the condition that requires that if an agreement provides for the services of an agent on a periodic, sporadic, or part-time basis, the contract must specify the schedule, length and exact charge for such intervals. OIG agreed with commenters that the removal of this requirement allows for greater flexibility in protected personal services arrangements, while continuing to incorporate safeguards that limit potential abuse.

    - The Safe Harbor was modified to protect certain "outcomes-based payments" so long as certain conditions are met. "Outcomes-based payments" are limited to "payments between or among a principal and an agent that: (A) reward the agent for successfully achieving an outcome measured described paragraph (d)(2)(i) [of the Safe Harbor]; or (B) recoup from or reduce payment to an agent for failure to achieve an outcome measure described in paragraph (d)(2)(i) [of the Safe Harbor]." The agreement must be set out in writing and signed by the parties in advance of, or contemporaneous with, the commencement of the terms of the outcomes-based payment arrangement.

- **Warranties (42 C.F.R. § 1001.952(g)):** OIG is finalizing its modifications to this Safe Harbor to promote higher-value items covered by such warranties.

    - In the Final Rule, OIG is extending the Safe Harbor to protect warranties that warranty a bundle of items or a bundle of one or more items and services. Although this revision now protects warranties covering services, it is significant to note that it does not provide protection to warranties that warranty only services.

        - Note that the Final Rule protects warranties that apply to one or more item and related services only if the federally reimbursable items and services subject to the warranty arrangement are reimbursed by the same federal health care program and in the same federal health care payment.

- OIG clarified that warranty remuneration for any medical, surgical, or hospital expense incurred by a beneficiary is capped at the cost of the items and services subject to the warranty.

- OIG also incorporated a new safeguard into the Safe Harbor by precluding warranty arrangements from being conditioned on the exclusive use or minimum purchase of one or more items or services, noting that this provides "important protection against patient steering that could interfere with clinical decision-making and against potential anticompetitive effects."

- OIG finalized a definition of "warranty" without reference to 15 U.S.C. § 2301(6), which explicitly clarifies that the Safe Harbor applies to FDA-regulated drugs and devices, and it would allow for single-item and bundled warranties.

- **Electronic Health Records ("EHR") Items and Services (42 C.F.R. § 1001.952(y)):** OIG removed the sunset provision in this Safe Harbor, which previously required that all protected EHR donations occur on or before Dec.31, 2021, in order to permanently provide for the protection of donations of EHR items and services.

  - The Final Rule modifies the definition of "electronic health record" to mean "a repository of electronic health information that: (A) is transmitted by or maintained in electronic media; and (B) relates to the past, present or future health or condition of an individual or the provision of healthcare to an individual."

  - OIG clarified that the Safe Harbor explicitly protects cybersecurity software and services so long as all conditions are satisfied.

  - The Final Rule expands the scope of protected donors (e.g., parent companies of hospitals, health systems, and accountable care organizations).

  - OIG clarified that for a donation to be protected, it must be interoperable and should not inappropriately interfere with, prevent, or materially discourage access, exchange or use of electronic health information.

- **Local Transportation (42 C.F.R. § 1001.952(bb)):** OIG finalized its proposal to expand the distance to which residents of rural areas may be transported from 50 to 75 miles, and removed any mileage limit on transportation furnished to a patient who has been discharged from a facility after admission as an inpatient or when a patient is discharged after spending 24 hours in observation status, regardless of whether the patient resides in an urban or rural area, so long as the transportation is to the patient's residence or another residence of the patient's choice.

  - In the Final Rule, OIG clarified that for purposes of this Safe Harbor, "residence" includes custodial care facilities that may serve as a patient's permanent or long-term residence, provided that the patient established the custodial care facility as a residence prior to receiving treatment by the facility from where the patient is being

transported. OIG also confirmed that a "residence of the patient's choice" may include the residence of a friend or relative who is caring for the patient post-discharge.

- OIG clarified that the new safe harbor at 42 C.F.R. § 100.952(hh) which protects certain patient engagement tools and support, includes transportation when the offeror of the transportation is a VBE participant. If the Safe Harbor's conditions are satisfied, this could protect transportation of patients from an inpatient hospital to another health care facility for post-acute care treatment. However, the OIG expressed concern when facilities are in a position to refer to each other, explaining that such referral relationship is not sufficiently low risk to warrant safe harbor protection.

- OIG declined to extend this Safe Harbor to protect patient transportation for non-medical purposes, noting that the risk of beneficiaries being improperly induced to obtain items or services is too high for safe harbor protection in this instance.

- OIG clarified that eligible entities may make transportation available through ride-sharing arrangements or through other means of local transportation that may exist in the future (e.g., self-driving cars), but declined to amend the regulatory text to specifically reflect this.

## B. Final Modifications to the Beneficiary Inducements CMP

The Beneficiary Inducements CMP prohibits any person from offering or transferring any remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services.[11] In 2000 and in 2016, the OIG codified final rules amending the term "remuneration" to exclude from its definition certain payment arrangements under the CMP beneficiary inducement provisions. In the Final Rule, the OIG set forth a new exception to the Beneficiary Inducements CMP:

- **Exception for Telehealth Technologies for In-Home Dialysis (42 C.F.R. § 1003.110):** OIG amended the definition of "remuneration" for the provision of certain telehealth technologies related to in-home dialysis services.

  - OIG defined "telehealth technologies" broadly to include items and services that facilitate telehealth services, noting that the goal is to protect a wide range of technologies to better support in-home dialysis. In the Final Rule, OIG also removed all references in this definition to specific types of technology, limits on the type of communication, and a requirement that telehealth services be paid for by Medicare Part B. This definition was also revised to clarify that "telehealth technologies" means hardware, software and services that support distant or remote communication between the patient and provider, physician, or renal dialysis facility for diagnosis, intervention or ongoing care management. All technologies would be protected (including telephones, facsimile machines, and electronic mail

systems), so long as all conditions of the exception are met; specifically, multimedia communications equipment, including audio and video equipment permitting two-way, real-time, interactive communication with the patient.

- A donation of technology may be protected under this exception if the telehealth technology is provided for the purpose of furnishing telehealth services related to the recipients' end-stage renal disease.

- The exception is available only to telehealth technologies furnished by a provider of services, physicians, or a rental dialysis facility currently providing in-home dialysis, telehealth services, or other ESRD care to the patients or has been selected or contracted by the patient to schedule an appointment or provide services.

- The telehealth technologies may not be offered as part of any advertisement or solicitation.

## C. Conclusion

The Final Rule was published in the Federal Register on Dec. 2, 2020 and will be effective January 19, 2021.

**Submitted by:** **Jamie B. Gelfman, Esq., and Timothy S. Wombles, Esq.,**
***Nelson Mullins Broad and Cassel***

## REGULATORY UPDATES

### Updates to the Florida Certificate of Need Process

To combat healthcare costs, most state governments have statutory requirements that certain healthcare institutions apply for and receive a Certificate of Need ("CON") from state agencies before: (i) erecting or replacing facilities or (ii) creating or expanding certain healthcare services.[12] Today, only twelve states do not have CON programs, and others, including Florida, have limited programs.[13] State governments administer CON programs under the assumption that too many underutilized healthcare facilities or services drive up healthcare costs.[14] Hospitals and other facilities may increase prices to account for more empty beds or unused services.[15] Some proponents of CON programs assert they are indispensable to slowing the proliferation of hospitals that are less inclined to provide care to indigent patients.[16] Alternatively, CON opponents argue that these CON programs inhibit competition and thus increase healthcare costs.[17]

In 1973, the Florida legislature enacted its CON process, under which the Agency for Health Care Administration ("AHCA") provides approval.[18] Statutory basis for Florida's CON program derives from the state's Health Facility and Services Development Act.[19]

Florida does not mandate CON applications for outpatient services, home health services, assisted living facilities, or purchases of major medical equipment.[20] Nonetheless, competing healthcare facilities still can challenge a CON application for other facilities and services, and successfully obtaining a CON is not a guarantee. In 2019, AHCA only approved 36 of 60 applications.[21] Additionally, CON application fees may be costly, ranging from $10,000 to $50,000.[22]

There are four batching cycles for CON applications each year, though each batching cycle is specific to certain types of facilities or service requested.[23] In each geographic region, AHCA calculates a predetermined medical need, but the onus falls upon CON applicants if they believe AHCA's assessment is incorrect.[24] Providing a robust argument requires considerable research, time, money, and other resources.

June 26, 2019 was Florida's most significant update to its CON program when Governor Ron DeSantis signed House Bill 21 ("HB 21").[25] This act previously was the focus of "Florida Eliminates the Certificate of Need Process for General Hospitals and Tertiary Services" in *March-April 2019 HLS Monthly Update*.[26] Although healthcare institutions remain subject to licensure requirements, HB 21 ended the CON program for many facilities and services.[27] Since July 1, 2019, CON applications are no longer necessary for Non-Restricted Facilities ("NRFs"): general hospitals, complex medical rehabilitation beds, and tertiary hospital services.[28] This also means that other competitors and incumbents can no longer oppose CON approvals.[29]

Starting July 1, 2021, all remaining hospitals will become NRFs and will no longer need to apply for a CON.[30] The hospitals that no longer require CON include Class II (specialty children's and women's hospitals), Class III (specialty medical, rehabilitation, and psychiatric hospitals as well as substance abuse hospitals), and Class IV hospitals (specialty hospitals that only offer Intensive Residential Treatment Facility Services for Children and Adolescents).[31]

Even after 2021, the CON requirement will remain intact for nursing homes, skilled nursing facilities, hospice centers, and intermediate care facilities for the developmentally disabled ("ICF/DDs").[32] However, on June 20, 2020, Governor DeSantis signed Senate Bill 1344 ("SB 1344").[33] Taking effect on July 1, 2020, SB 1344 carved out a narrow CON exception for ICF/DDs: these facilities can forgo the CON process if, in addition to meeting several other requirements pertaining to quality, each institution:

> (a) builds on a single site three (3) homes with eight (8) beds each (24 beds total),
> (b) devotes at least sixteen (16) of those beds to "individuals with severe maladaptive behaviors,"
> (c) has no licensure issues within the previous three (3) years, and
> (d) has at least ten (10) years of similar professional experience.[34]

Although hospitals and providers of tertiary services collectively will benefit the most from the CON elimination, Florida has many nursing homes, skilled nursing facilities, and hospice centers that will still be required to follow CON regulations.

AHCA canceled its second batching cycle in July 2020 due to the COVID-19 pandemic and has not indicated when its batching cycles will resume.[35] However, this cancellation likely will not materially affect Florida's ability to fight COVID-19, as the process for planning and building facilities takes time, even with the eradication of CON requirements for many. Nonetheless, there may be a backlog of applications into and perhaps past 2021.

**Submitted by: Gaurav J. Dhiman, J.D. Candidate, *University of Miami School of Law***

[1] *See* https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/SpecialFraudAlertSpeakerPrograms.pdf.
[2] *See* https://www.justice.gov/criminal-fraud/hcf-2020-takedown/press-release.
[3] Christianna L. Finnern, *Behavioral Health Enforcement and Compliance Insights from the 2020 National Health Care Fraud and Opioid Takedown*, AHLA, Oct. 30, 2020.
[4] *Id.*
[5] *See* 18 U.S.C. § 220(a).
[6] *U.S. v. Hernandez*, https://www.justice.gov/criminal-fraud/file/1321046/download; *U.S. v. Markovich*, https://www.justice.gov/criminal-fraud/file/1321041/download; *U.S. v. Ligotti*, https://www.justice.gov/criminal-fraud/file/1321036/download.
[7] This article was initially published, with slight modifications, on Nelson Mullins' website on November 24, 2020, and is available at: https://www.nelsonmullins.com/idea_exchange/blogs/healthcare_essentials/federal-healthcare-policy-developments/oig-finalizes-coordinated-care-revisions-to-the-anti-kickback-statute-and-civil-monetary-penalties-law.
[8] 84 Fed. Reg. 55,694 (Oct. 17, 2019).
[9] 42 U.S.C. § 1320a-7b(b).
[10] The value-based Safe Harbors will be effective Jan. 31, 2021.
[11] 42 U.S.C. § 1320a-7a(a)(5).
[12] 40A Am. Jur. 2d Hospitals and Asylums § 6.
[13] Florida Hospital Association, *Certificate of Need*, Fla. Hosp. Ass'n, http://www.fha.org/Advocacy/State-Advocacy/Legislative-Issues/Certificate-of-Need.aspx (last visited Oct. 2, 2020) (hereinafter "FHA").
[14] National Conference of State Legislatures, *CON-Certificate of Need State Laws*, Nat'l Conference of State Legislatures, http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx (last visited Oct. 11, 2020) (hereinafter "NCSL").
[15] Becker's Hospital Review, *10 Statistics Your Hospital Should Track*, Becker's Hosp. R., https://www.beckershospitalreview.com/hospital-management-administration/10-statistics-your-hospital-should-track.html (last visited Nov. 10, 2020).
[16] *Id*.
[17] NCSL, *supra* note 14.
[18] FHA, *supra* note 13.
[19] FLA. STAT. §§ 408.032-408.045.
[20] Agency for Health Care Administration, *Certificate of Need (CON) Program Overview*, Agency for Health Care Admin., https://ahca.myflorida.com/mchq/con_fa/ (last visited Nov. 8, 2020) (hereinafter "AHCA").
[21] AHCA, *CON Decisions & State Agency Action Reports*, Agency for Health Care Admin., https://ahca.myflorida.com/mchq/con_fa/batching/decisions.shtml (last visited Nov. 10, 2020).
[22] FLA. STAT. § 408.038.
[23] FLA. ADMIN. CODE r. 59C-1.008(1).
[24] AHCA, *supra* note 20.
[25] Fla. CS for HB 21 (2019) (proposed FLA. STAT. §§ 408.032-408.045), https://www.flsenate.gov/Session/Bill/2019/21/BillText/er/PDF (hereinafter "HB 21").
[26] Trish Calhoun, *March-April 2019 HLS Monthly Update*, Health Law Section of the Florida Bar, http://www.flabarhls.org/resources-menu/document-library/health-law-updates/338-hls-monthly-updates-2019-march-april-updated (last visited Nov. 1, 2020).
[27] HB 21, *supra* note 25 at 1.
[28] *Id*. at 9.
[29] *Id*. at 32.
[30] *Id*. at 26.
[31] Health Policy Committee, *CS/HB 21 - Hospital Licensure (Bill Summary)*, Health Policy Comm., https://www.flsenate.gov/Committees/BillSummaries/2019/html/2068.
[32] HB 21, *supra* note 25 at 11.
[33] Fla. CS for SB 1344 (2020) (proposed Fla. Stat. § 408.036), https://www.flsenate.gov/Session/Bill/2020/1344/BillText/er/PDF.
[34] *Id*. at 3.
[35] AHCA Order 20-004 (Jul. 17, 2020), https://ahca.myflorida.com/MCHQ/CON_FA/overview/Emergency_Order20-004.pdf.