HEALTHCARE REGULATORY CHECK-UP

IN THIS ISSUE

This issue of McDermott's *Healthcare Regulatory Check-Up* highlights significant activity between June 21 and July 20, 2022. During this period, the Supreme Court of the United States overturned *Roe v. Wade*, which historically recognized the constitutional right to abortion, in *Dobbs v. Jackson Women's Health Organization*. This decision has legal implications for virtually all healthcare organizations. The Supreme Court also upheld the US Department of Health & Human Services (HHS) regulations regarding the disproportionate share hospital (DSH) payment formula, finding that individuals "entitled to Medicare Part A benefits" are all individuals qualifying for the program and not just those whose hospital bills were actually paid by Medicare. This issue also reviews several criminal and civil enforcement actions related to Anti-Kickback Statute (AKS) and beneficiary inducement issues, as well as false claims allegations.

In addition to examining recent Office of Inspector General (OIG) advisory opinions, we offer an update on the OIG's Special Fraud Alert providing guidance on telemedicine arrangements and OIG's Annual Health Care Fraud and Abuse Control Program Report. We also examine recently published Centers for Medicare & Medicaid Services (CMS) rules and guidance regarding innovation models, the Clinical Laboratory Improvement Amendments of 1998 (CLIA) regulations, and long-term care facilities requirements.

NOTABLE ENFORCEMENT RESOLUTIONS AND ACTIVITY

PAIN SPECIALIST SETTLES ALLEGATIONS OF RECEIVING KICKBACKS FROM PHARMACEUTICAL COMPANIES

A California-based pain specialist paid more than $271,000 to resolve allegations that he violated the False Claims Act (FCA). The allegations concerned prescription of certain medications to Medicare beneficiaries in exchange, at least in part, for receiving paid speaking and consulting work from the drugs' manufacturers.

HOSPITAL SETTLES FCA VIOLATION ALLEGATIONS FOR $1.5M

A West Virginia hospital agreed to pay $1.5 million to resolve allegations that it violated the FCA by knowingly submitting or causing the submission of claims to Medicare in violation of the Stark Law due to payment of compensation to referring physicians that allegedly exceeded fair market value or took into account the volume or value of the physicians' referrals to the hospital.

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PHARMACY ENTERS INTO DEFERRED PROSECUTION AGREEMENT OVER FALSE CLAIMS

A Florida-based pharmacy entered into a deferred prosecution agreement and agreed to pay a $1.31 million civil settlement to resolve allegations that it submitted fraudulent claims to Medicare for a drug used in rapid reversal of opioid overdoses. According to the pharmacy's admissions in the criminal and civil agreements, the pharmacy completed prior authorization forms for the drugs in place of the prescribing physicians. In some cases, pharmacy staff signed the forms without a physician's authorization and listed the pharmacy's contact information as if it were a physician's information. The pharmacy also submitted prior authorization requests for the drug that contained false clinical information to secure approval. Finally, the pharmacy waived Medicare beneficiary copayment obligations for the drug on many occasions without analyzing whether the patient had a genuine financial hardship. The pharmacy and its CEO also entered into a three-year integrity agreement with OIG.

ADDICTION TREATMENT FACILITIES MEDICAL DIRECTOR SENTENCED TO PRISON OVER $112M FRAUD SCHEME

A Florida-based medical director of addiction treatment facilities was sentenced to 54 months in prison for engaging in a scheme that fraudulently billed approximately $112 million for substance abuse services that were never provided or were medically unnecessary. According to evidence produced during trial, the medical director and others admitted patients for medically unnecessary detox services. Patient recruiters offered kickbacks to induce patients to attend the programs, then gave them illegal drugs to ensure they stayed admitted for detox services. The medical director submitted false and fraudulent claims for excessive, medically unnecessary urinalysis drug tests that were never used in treatment. The medical director and others authorized the re-admission of a certain group of patients who were referred between two facilities to allegedly bill for as much treatment as possible, even though the treatment was not medically necessary. The medical director also prescribed patients a drink to sedate them, ensure they stayed at the facility and keep them coming back. Finally, the medical director's log-in information was used, with his knowledge, by others to sign electronic medical files to make it appear as if he had provided treatment himself when he had not.

SKILLED NURSING FACILITY OPERATOR SETTLES FALSE CLAIMS ALLEGATIONS FOR $11.2M

A Georgia-based skilled nursing facility operator settled with North Carolina and 22 other states for $11.2 million to resolve allegations that the operator violated the FCA and the North Carolina False Claims Statute and cause the submission of false claims to the North Carolina Medicaid program. The operator allegedly engaged in a scheme to maximize billing that improperly caused therapists to provide Medicare and Medicaid beneficiaries with rehabilitation therapy that was either not reasonable and necessary, not skilled, or not covered by the Medicare Part A and Medicaid coinsurance benefits. Some of the nursing services provided by the operator allegedly were grossly and materially substandard, partly because the operator failed to provide care that met federal requirements to some of its residents.

SPINE DEVICE DISTRIBUTOR SETTLES LAWSUIT ALLEGING ILLEGAL PHYSICIAN KICKBACKS FOR $1M

A Utah-based spinal implant device distributor, its owners and two physician-owned distributorships associated with the distributor agreed to pay $1 million to resolve allegations that they violated the FCA by paying physicians to use the distributor's medical devices in spinal surgeries. The US Department of Justice (DOJ) contended that the physician-owned distributorships paid physicians based on their referrals, made false statements to healthcare providers and terminated physicians who did not refer enough patients.

INSURANCE COMPANY SETTLES ALLEGED FCA VIOLATIONS FOR $4.2M

An insurance company agreed to pay $4.2 million to resolve allegations that it implemented a gift card incentive program in violation of the AKS. The company distributed 1,703 gift cards to providers' administrative assistants at an aggregate cost of $42,575 to allegedly induce the assistants to refer, recommend or arrange for enrollment of 1,646 new Medicare beneficiaries to a company Medicare Advantage plan. As a result of the new Medicare beneficiaries, the company received associated premium payments.

NURSING HOME HEALTH SYSTEM SETTLES ALLEGED FCA VIOLATIONS RELATED TO COVID-19 VACCINATIONS FOR $1.75M

A nursing home health system agreed to pay $1.75 million to resolve its potential liability under the FCA for facilitating COVID-19 vaccinations for hundreds of individuals ineligible to participate in the Centers for Disease Control and Prevention (CDC) Pharmacy Partnership for Long-Term Care Program (LTC PPP). The LTC PPP was specifically designed to vaccinate long-term care facility (LTCF) residents and staff when doses of COVID-19 vaccines were in limited supply at the beginning of the CDC COVID-19 Vaccination Program. The government alleged that the nursing home health system knew that the LTC PPP covered only LTCF residents and staff but nevertheless invited and facilitated the vaccination of hundreds of ineligible persons at the clinic by characterizing them as "staff" and "volunteers," many of whom the nursing home health system targeted for donations. The government alleged that the nursing home health system characterized board members as "staff," directed the organization's fundraising arm to invite donors and potential donors to the vaccination clinic, and allowed the board's vice chairman and his brother to invite almost 300 ineligible individuals to receive the vaccine at the system's facilities.

NURSE PRACTITIONER PLEADS GUILTY TO CONSPIRACY IN $15M DME SCHEME

A North-Carolina-based nurse practitioner who worked for a telemedicine company pled guilty to conspiracy in a durable medical equipment (DME) scheme. Under the scheme, the practitioner allegedly caused the submission of false claims to Medicare for almost $15 million for medically unnecessary orthopedic braces and other DME. He did this by signing false medical records describing purported "assessments" of Medicare beneficiaries, and by certifying that he had performed corresponding medical examinations when he had no interaction with the beneficiaries and made no medical determination whether the devices were medically necessary or whether the beneficiaries needed the DME. He received unsigned orders from the telemedicine company for orthopedic braces for the beneficiaries. He signed and returned these orders to the telemedicine company in exchange for $15 for each purported assessment that he performed. A sentencing date for the nurse practitioner has not yet been set.

PHARMACEUTICAL COMPANY OPERATOR SENTENCED TO PRISON, AGREES TO PAY $950K FOR ALLEGED FCA VIOLATIONS

A Georgia-based man was sentenced to five years in prison and agreed to pay $950,000 as part of an "ability to pay" civil settlement to resolve allegations that he violated the FCA by causing false claims for DME and compound prescription medications to be submitted to the Medicare program. The man operated a pharmaceutical company that caused compounding pharmacies to submit false claims for these prescriptions to Tricare. The compounding pharmacies paid the pharmaceutical company a portion of the Tricare reimbursement, and the pharmaceutical company paid a portion of its proceeds to healthcare marketing companies that pushed providers to prescribe unnecessary compound medications. The man and others at the pharmaceutical company used claims data to track the referrals made to compounding pharmacies and to invoice those pharmacies for the illegal kickbacks owed to the pharmaceutical company for the referrals. The man also worked with owners of DME supply companies to submit false claims for medically unnecessary DME orders, which were supported by telemedicine physicians who, in many instances, never spoke with or examined the Medicare beneficiaries for whom the physicians ordered DME. The man received $5-$15 plus a percentage of all Medicare reimbursement for each piece of DME he shipped.

SKILLED NURSING FACILITY, NURSING HOME SETTLE ALLEGATIONS OF FRAUDULENTLY SWITCHING RESIDENTS' HEALTHCARE COVERAGE TO BOOST MEDICARE PAYMENTS FOR $7.85M

A New-York-based skilled nursing facility and nursing home agreed to pay $7.85 million to the US government and made factual admissions regarding allegations that they fraudulently switched the type of Medicare coverage in which elderly residents were enrolled in order to maximize the Medicare payments that the nursing home would receive. The skilled nursing facility and nursing home admitted that their staff often did not obtain the consent of the resident or the resident's authorized representatives prior to disenrolling the resident from a Medicare Advantage Plan. As part of the settlement, the skilled nursing facility agreed to take steps to ensure that all of its locations comply with applicable guidance on Medicare health plan disenrollments and enrollments. The skilled nursing facility and nursing home also entered into a corporate integrity agreement with OIG that requires them to maintain a compliance program designed to foster adherence to federal healthcare program requirements.

PHARMACIES SETTLE ALLEGED FCA VIOLATIONS BY FRAUDULENT USE OF COLLABORATIVE PHARMACY PRACTICE AGREEMENTS

Three Florida-based pharmacies agreed to pay more than $830,000 to resolve allegations that they fraudulently used collaborative pharmacy practice agreements to delegate prescribing authority from physicians to pharmacists, resulting in unlawful prescriptions, and used the same collaborative practice agreements to write and fill prescriptions without any physician involvement. The fraudulent scheme allegedly resulted in the submission of false claims to federal healthcare programs, including Medicare and Medicaid.

OIG ADVISORY OPINIONS

ADVISORY OPINION 22-13, POSTED ON JUNE 23, 2022

The requestor is a DME manufacturer that sells its products to DME supplier customers, some of whom dispense the products to federal healthcare program beneficiaries. The requestor entered into agreements with two third-party financial institutions to make zero-interest financing available to customers, subject to certain terms and conditions described in the lenders' loan documents with approved customers. The requestor certified that, at some point before or after a customer's payment is due to the requestor pursuant to the invoiced terms, the customer may contact or be contacted by the requestor's credit and collections personnel. If a customer does not pay the requestor the full amount of an invoice that is due, the customer may request (or the requestor's credit and collections personnel may offer) the opportunity to seek financing from a lender.

Under the arrangement, the requestor's credit and collections personnel may refer to a lender any interested customer that owes or will owe at least $10,000 to the requestor, is in good standing with the requestor and is an acceptable credit risk, as reasonably determined by the requestor. The requestor does not advertise the potential for zero-interest financing in its marketing materials, nor does the requestor guarantee to any customer or potential customer that zero-interest financing will be available from a lender. Once the requestor learns that a customer desires zero-interest financing and meets the above-referenced criteria, the requestor's credit and collections personnel contact one of the lenders. That lender performs its own creditworthiness analysis to decide independently whether to offer financing to the particular customer. If approved, the financing agreement is between the applicable lender and the customer. The requestor certified that the typical financing agreement between a lender and a customer results in a loan that is for one year at 0% interest and requires that the customer make payments to the lender in 12 equal installments. The lender pays the requestor the invoiced amount that the customer owes to the requestor, minus an amount that the lender retains (the finance charge) based on rates set forth in the agreement between the requestor and the lender (*e.g.*, 3% of the loan value).

Although each lender has the sole right and responsibility to collect payment from customers with whom the lender enters into financing agreements, and customers remain liable only to the lender, the agreement between each lender and requestor under the arrangement establishes a "loss pool" to allocate responsibility between the applicable lender and the requestor in the event of a customer default. The loss pool allocations are different for each lender, but in each case the loss pool is based on the total dollar amount of customer contracts funded by the lender in a particular year.

OIG ANALYSIS

OIG stated that although making zero-interest financing available to eligible customers constitutes remuneration and implicates the AKS, it poses sufficiently low risk of fraud and abuse under the AKS for the following reasons:

- Although arranging for zero-interest financing is remuneration and a clear benefit for customers, the customers do not receive a discount or other price concession from the requestor under the agreements (except for those customers that default on their loans, which occurs with only 2.5% or less of the total amount financed on behalf of customers across all lenders' loans).

- The involvement of risk-bearing lenders in the arrangement reduces the risk associated with providers, suppliers or manufacturers that might offer, subsidize or forgive loans to secure future referrals. The lenders perform their own creditworthiness analysis on each customer-applicant and decide themselves whether to enter into a financing agreement. The lenders also collect payments under the financing agreements and, if applicable, bear the first and third layers of responsibility for defaulted loans.

- The requestor's agreement with the lenders to receive less than the total amount owed by the customer (in the form of a finance charge) does not increase the risk of fraud and abuse under the AKS. The lenders are not healthcare providers or suppliers, and they are not in a position to refer federal healthcare program business to the requestor.

- The agreements present a sufficiently low risk with respect to many of the other fraud and abuse concerns that OIG considers when examining arrangements under the AKS, such as the following:

    - The agreements should not result in increased costs to federal healthcare programs because the items are reimbursed based on fee schedule amounts, regardless of the amount DME suppliers pay to acquire them.

    - Because DME suppliers do not prescribe equipment, the agreements should not result in overutilization.

    - Although facilitating zero-interest financing might give the requestor a competitive advantage over other manufacturers that do not have similar arrangements, OIG believes this factor presents limited risk of fraud and abuse under the AKS, particularly because the requestor does not market the possibility of, or guarantee access to, zero-interest loans, and the sales representative's commission is reduced if a customer receives zero-interest financing.

- Because the requestor assumes partial liability in the event that customers default on the loans, the requestor's incentive to initiate the zero-interest financing by contacting a lender on behalf of customers who may be unlikely to pay their obligations is limited, as is the lenders' incentive to approve such requests. The lenders also use their own personnel to engage in the same collection and enforcement activities to collect the amount due from each customer as the lender would use for any other debt. In the event of a default following such collection efforts, the customer would have no reason to know if the requestor subsidized part of a default through the loss pool.

ADVISORY OPINION 22-14, POSTED ON JUNE 29, 2022

The requestor is an ophthalmology practice with one ophthalmologist performing surgical procedures and three optometrists providing primary eye care in support of these surgeries. The requestor estimates that local optometrists outside of the practice refer half of the surgical procedures requestor performs, and 30% of those patients return to the referring optometrist for post-operative care that is co-managed with the requestor's ophthalmologist.

The requestor proposed hosting continuing education (CE) programs for optometrists in the requestor's service area. Under the proposed arrangements, the requestor would offer, on an annual basis, two CE programs that would address new technology and pharmacological practice treatment protocols relevant to treating patients who require ophthalmic surgeries, including the requestor's patients. The course options would consist of a full-day CE program providing six hours of CE credit and an evening CE program providing two hours of CE credit. The CE programs would be open to all local optometrists in the requestor's service area, which comprises an approximately 20-mile radial area. Attendance would not be limited to optometrists who refer to the requestor, and there would be no requirement that attendees refer patients to the requestor as a condition of attendance. The selection of attendees also would not be based on past or expected prescribing or ordering of any industry sponsor's items or services payable by federal healthcare programs. The requestor estimates that 100 optometrists would attend the full-day program, and 30 to 50 optometrists would attend the evening program. The requestor's ophthalmologist and optometrists would serve as faculty. Additional faculty for the full-day program would include one or two faculty members from professional schools. These external faculty would be paid an honorarium plus expenses at a fair market value rate that would not take into account the volume or value of past business generated or potential future business generated for the requestor or for an industry sponsor by the faculty.

The requestor asked OIG to opine on four potential funding options:

- The requestor would cover all CE program costs and charge attendees a fair market value registration fee (proposed arrangement A).
- The requestor would cover all CE program costs with no registration fee or outside funding (proposed arrangement B).
- The requestor would not charge any registration fee to CE program attendees, and industry sponsors such as medical device and pharmaceutical companies would fund some or all of the CE program costs. The requestor would fund any shortfall or donate any sponsorship funds that exceeded the program costs to a local charity. (proposed arrangement C).
- The requestor would charge a registration fee to CE program attendees that would be subsidized by the funding received from industry sponsorships for the programs. The requestor would fund any shortfall or donate any sponsorship funds that exceeded the program costs to a local charity (proposed arrangement D).

OIG ANALYSIS

OIG stated that all four arrangements would implicate the AKS because the requestor would give something of value (the CE programs) to local optometrists who are positioned to refer patients, including federal healthcare program beneficiaries, to the requestor for surgery. Additionally, under proposed arrangements C and D, the requestor, external faculty members and attendees would receive remuneration from industry sponsors that may, in turn, receive orders for their products from the requestor, external faculty members and attendees.

OIG referenced its 2020 Special Fraud Alert (SFA) regarding speaker programs, which highlights the risks associated with speaker programs organized and paid for by pharmaceutical and medical device companies for healthcare professionals (HCPs). Although OIG recognized the differences between speaker programs and the proposed arrangements, OIG stated that the following suspect characteristics identified in the SFA may be instructive.

SFA Suspect Characteristics	Requestor's CE Programs
A company sponsors a speaker program where little or no substantive information is actually presented.	• CE program content would address new technology and pharmacological practice treatment protocols relevant to treating patients who require ophthalmic surgeries, including the requestor's patients. • Faculty, which would include the requestor's physicians, would possess first-hand professional experience that enables them to provide expertise and input on the CE program topics. • The CE programs would be approved for CE credit by an appropriate professional CE certification board.
Alcohol is available, or a meal exceeding modest value is provided to attendees.	Only modest food items, such as bagels, coffee, pizza and non-alcoholic refreshments, would be provided.
The program is held at a location not conducive to the exchange of educational information.	The venue would be one of the requestor's offices or another appropriately sized conference space conducive to educational presentations in a geographic location convenient to the requestor's service area.
Selection of HCP speakers or attendees is based on past or expected revenue that these individuals have generated or will generate by prescribing or ordering the company's products.	• The CE programs would be open to all local optometrists. Attendance would not be limited to optometrists who refer to the requestor, and there would be no requirement that attendees refer patients to the requestor as a condition of attendance. • Neither the selection of attendees nor the selection of external faculty would be based on referrals to the requestor or past or expected prescribing or ordering of any industry sponsor's items or services payable by federal healthcare programs.
A 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.	External faculty would be paid an honorarium plus expenses at a fair market value rate that would not take into account the volume or value of past business generated or potential future business generated for the requestor or for an industry sponsor by the faculty presenter.

Although OIG stated that, generally, none of the proposed arrangements exhibit the types of suspect characteristics highlighted in the SFA, proposed arrangement A would pose a sufficiently low risk of fraud and abuse under the AKS, and proposed arrangements B, C and D would present more than a minimal risk.

- Proposed arrangement A: Here, the requestor would charge attendees a registration fee consistent with fair market value for such CE programs. To the extent revenue generated from the fair market value registration fees does not cover the CE programs' expenses, the requestor would cover those costs. Conversely, to the extent the revenue from the registration fees exceeds the CE programs' expenses, the requestor would donate the excess amount to a local charity. The requestor certified that the registration amounts it proposes to charge and the anticipated number of attendees comport with the estimated amount of expenses, such that any revenue shortfall or overage should not be substantial. In this scenario, and in combination with the low risk aspects of the program, OIG concluded this arrangement presented sufficiently low risk.

- Proposed arrangement B: OIG stated that because this arrangement involves the provision of free goods or services to an existing or potential referral source, that, have independent value and these goods or services have independent value to the recipient, there is heightened risk that this remuneration could induce the optometrist attendees and external faculty to refer surgical patients, including federal healthcare program beneficiaries, to the requestor, which could result in inappropriate patient steering.

- Proposed arrangement C: OIG stated that because this arrangement involves the provision of free goods or services to an existing or potential referral source, that, have independent value and these goods or services have independent value to the recipient, there is heightened risk that this remuneration could induce the requestor, external faculty and the optometrist attendees to prescribe or order a sponsoring company's products, including those payable by federal healthcare programs, which could result in inappropriate patient steering or inappropriately increased costs to federal healthcare programs.

- Proposed arrangement D: OIG highlighted the fact that the requestor is an ophthalmology practice and potentially a direct referral source for sponsoring medical device and pharmaceutical companies, in contrast with more traditional CE program organizers that often are independent entities not directly involved in the provision of patient care (*e.g.*, a professional organization). By paying sponsorships to the requestor to fund its CE programs, the medical device manufacturers and drug companies would pay expenses that the requestor otherwise would incur.

We provide further analysis of this opinion here.

ADVISORY OPINION 22-15, POSTED JULY 5, 2022

The requestors are universities that propose to use *bona fide* charitable contributions to furnish specialized, medically necessary care to US military service veterans who meet certain criteria, and to provide financial assistance to such veterans related to care provided at or arranged by a requestor. One requestor (University A) includes two entities:

- A school of medicine that is a component of an academic medical center, employs the university's physicians and non-physician practitioners, and operates an institute that is part of the proposed arrangement

- A management entity that provides support for the education, research and patient care mission of the school of medicine and participates in federal healthcare programs as a clinic location.

The other requestor (University B) employs the physician and non-physician practitioners of the university medical group, who are enrolled in federal healthcare programs. University B intends to provide the services in the proposed arrangement at its medical group clinics, which is a component of an academic medical center.

Under the proposed arrangement, University A's institute and University B's clinics (collectively, clinical programs) provide intensive outpatient treatment and specialty care for US military service veterans with mild-to-moderate traumatic brain injuries and associated physical and psychological health conditions connected to their military service, including post-traumatic stress. The requestors would use charitable donations from certain donors to cover expenses veterans would incur while receiving evaluation and treatment by the clinical programs, including out-of-pocket costs for treatment related to a veteran's traumatic brain injury, head injury or post-traumatic stress diagnosis (whether provided directly by the clinical programs or by a third party) and travel-related expenses. Donors contributing to the proposed arrangement would be individuals and organizations that support veterans' needs and would not be individuals or entities in the healthcare industry, including entities that manufacture or furnish items or render services that are billable to federal healthcare programs.

OIG ANALYSIS

OIG stated that the proposed arrangement would implicate the AKS and the beneficiary inducements civil monetary penalty law (Beneficiary Inducements CMP). OIG explained that the requestors would offer remuneration to veterans who receive treatment from the clinical programs by using donations to cover veterans' cost-sharing amounts otherwise owed for billable items and services; out-of-pocket costs for non-covered items and services; and certain travel, lodging and meals for which no AKS exception or safe harbor would apply. Although certain aspects of the remuneration could fall under the Beneficiary Inducements CMP exception for remuneration that promotes access to care and poses a low risk of harm (*e.g.*, the travel assistance), no exception would protect other aspects of the remuneration (*e.g.*, the cost-sharing subsidies, particularly without an individualized financial need determination). However, for the following reasons, OIG concluded that the proposed arrangement would present a minimal risk of fraud and abuse under the AKS, and stated that it would not impose sanctions under the beneficiary inducements CMP:

- The proposed arrangement would be unlikely to increase costs inappropriately for federal healthcare programs and could result in overall cost savings because some of the services offered would not be federal healthcare program billable services and the requestors expect the clinical programs' treatment to address unmet health needs that, without appropriate treatment, could lead to overutilization of covered services.
- Donors would not have a financial interest in veterans obtaining any particular items or services, because donors would not be involved in the healthcare industry and, specifically, would not manufacture or furnish items or render services that are billable to federal healthcare programs.
- Although the proposed arrangement could induce veterans to receive certain services from the requestors that they might have received elsewhere (or not have received at all), there is a low risk that it would induce veterans to receive any services from requestors outside of those offered through the clinical programs. The proposed arrangement is designed to enable veterans to access the services of the clinical programs, not other covered services that are not part of the clinical programs. Veterans would return to their home communities after the three-week program, so any future treatment for both related and unrelated conditions most likely would be from healthcare providers in those communities rather than from requestors.
- The requestors would not advertise the availability of financial assistance in connection with the clinical programs. All veterans who meet the clinical criteria to receive treatment from the clinical programs would receive treatment and transportation at no cost to them, regardless of financial need or insurance status.
- The proposed arrangement would be unlikely to result in "leapfrogging" concerns because active-duty service members could receive similar services through other programs at no cost, which would not be available to veterans who would qualify for services under the proposed arrangement, and because to the requestors' knowledge, no other entities provide a similar, coordinated suite of services. Therefore, the requestors' subsidization of out-of-pocket costs for care, travel, lodging and meals for the veterans and their family members appears to be a reasonable means to facilitate veterans' access to these services.

OTHER NOTABLE DEVELOPMENTS

DOBBS DECISION: THE OVERTURNING OF *ROE V. WADE*

On June 24, 2022, the Supreme Court of the United States issued its decision in *Dobbs v. Jackson Women's Health Organization*, overturning *Roe v. Wade*. In *Dobbs*, the Court held that "[t]he Constitution does not confer a right to abortion; *Roe* and [*Planned Parenthood v. Casey*] are overruled; and the authority to regulate abortion is returned to the people and their elected representatives." As noted in our recent article, organizations whose operations touch family planning services in any way should immediately examine their precise services, geographic footprint, corporate structure and organizational priorities. These organizations include not only providers that furnish pregnancy termination services, but also those that provide advice, operational support or other assistance to providers. We have created a Post-*Roe* Mitigation Checklist to help organizations navigate this complex topic.

OIG SPECIAL FRAUD ALERT: TELEMEDICINE ARRANGEMENTS

On July 20, 2022, OIG issued a Special Fraud Alert warning providers to exercise caution when entering into arrangements with telemedicine, telehealth and telemarketing companies. The Special Fraud Alert identifies seven suspect characteristics in such arrangements. We provide the full details of the Special Fraud Alert here.

SUPREME COURT UPHOLDS HHS INTERPRETATION OF DSH PAYMENT FORMULA

In *Becerra v. Empire Health Foundation*, The Supreme Court reversed the judgment of the US Court of Appeals for the Ninth Circuit, which found that an HHS regulation regarding the Medicare fraction for DSH payments was inconsistent with the statutory description. The Supreme Court found that for purposes of calculating the Medicare fraction (one of two fractions the Medicare program uses to adjust the rates paid to hospitals that serve a higher-than-usual percentage of low-income patients), individuals "entitled to Medicare Part A benefits" are all individuals qualifying for the program, regardless of whether they receive Medicare payments for part or all of a hospital stay. The regulation effectively decreases the amount of additional Medicare payments hospitals receive for serving a larger share of low-income patients.

HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT

OIG released its FY 2021 Health Care Fraud and Abuse Control Program Annual Report. The report highlights the more than $5 billion won or negotiated by the federal government in healthcare fraud judgments and settlements, and provides a detailed overview of HHS and DOJ's enforcement activities. In FY 2021, DOJ opened 831 new criminal healthcare fraud investigations and 805 new civil healthcare fraud investigations. OIG reported that 1,689 individuals and entities were excluded from federal healthcare programs in FY 2021. OIG also reported that in FY 2021, CMS developed a robust fraud risk assessment process that addressed the potential fraud risks associated with the COVID-19 public health emergency waivers and flexibilities, including unnecessary laboratory testing, healthcare technology schemes and fraudulent obtainment of COVID-19 healthcare relief funds.

CMS INNOVATION CENTER: ENHANCING ONCOLOGY MODEL AND AKS SAFE HARBORS

CMS published a Request for Application (RFA) for the CMS Innovation Center's Enhancing Oncology Model, which aims to improve care and coordination in oncology care for Medicare beneficiaries. Under the Enhancing Oncology Model, participating oncology practices will take on financial and performance accountability for episodes of care surrounding systemic chemotherapy administration to patients with common cancer types. The Enhancing Oncology Model is a five-year voluntary model, beginning on July 1, 2023. In preparation, CMS has determined that the AKS safe harbors for CMS-sponsored model arrangements and in-kind patient incentives will be available beginning July 1, 2023, to protect certain pooling arrangements, care partner arrangements and incentives.

CLIA PROFICIENCY TESTING UPDATES

CMS and CDC published a final rule updating proficiency testing regulations under CLIA. The final rule updates the proficiency testing requirements for microbiology testing, non-microbiology specialties and subspecialties, and regulatory definitions. CMS and CDC estimate that the final rule will affect 35,967 clinical laboratories subject to participation in proficiency testing. The final rule will take effect on August 10, 2022.

LONG-TERM CARE FACILITY REQUIREMENTS

On June 29, 2022, CMS published updated surveyor guidance for nursing home surveyors that clarifies requirements and how compliance will be assessed. CMS made several revisions and clarifications including the following:

- Revision to Phase 2 guidance that incorporates the use of Payroll Based Journal staffing data submitted by providers to help inform surveyors of potential staffing concerns
- Clarification related to the requirement that all facilities have an infection preventionist
- Guidance related to arbitration agreements that prohibits facilities from requiring residents to sign binding arbitration agreements as a condition of admission to the facility or as a requirement to continue to receive care at that facility.

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