Value-Based Arrangement Exceptions and Safe Harbors Have Narrow Utility for Medical Device and Pharmaceutical Companies

On December 2, 2020, the Department of Health & Human Services (HHS) published its long-awaited two final rules – one by the **Office of Inspector General** (OIG) and one by the **Center for Medicare & Medicaid Services** (CMS) – finalizing changes to regulations implementing the federal anti-kickback statute (AKS), the beneficiary inducement provisions of the civil monetary penalty law (CMPL), and the physician anti-self-referral law (Stark Law) and their safe harbors and exceptions. Among the most anticipated aspects of the final rules are the new value-based arrangement AKS safe harbors and Stark Law exceptions.

The two final rules, while complicated, are aligned in their definitions of value-based arrangements.

A **value-based enterprise (VBE)** is two or more participants that: (1) are collaborating to achieve at least one value-based purpose; (2) are each a party to a value-based arrangement with the other (or at least one other participant in the same VBE); (3) have an accountable body or person responsible for financial and operational oversight of the VBE; and (4) have a governing document describing the VBE and how its participants intend to achieve the VBE's value-based purpose(s).

A **value-based arrangement** is an arrangement entered into between (1) a VBE and one or more of its participants, or (2) among participants in the same VBE, for the provision of one or more value-based activities for a target patient population.

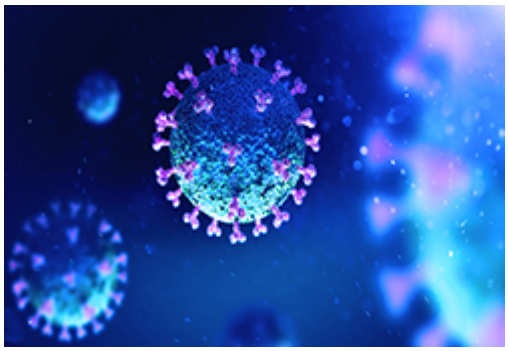
A **value-based purpose** is (1) coordinating and managing the care of a target patient population; (2) improving the quality of care for a target patient population; (3) appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or (4) transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

While the new AKS safe harbors exclude pharmaceutical and medical device manufacturers, distributors, and wholesalers; DMEPOS suppliers; laboratories; compounding pharmacies; and pharmacy benefit managers, there is a narrow exception intended to facilitate the deployment of health technologies for care coordination. These entities are eligible for protection under the care coordination safe harbor as "**limited technology participants**" that exchange "**digital health technology**" (defined broadly) with a VBE or VBE participant. The OIG Final Rule provided as an **example** "a medical technology company could partner with physician practices, to better coordinate and manage care for patients discharged from a hospital with digitally-equipped devices that collect and transmit data to the physicians to help monitor the patients' recovery and flag the need to intervene in real time (e.g., a device that monitors range of motion that could inform what

an appropriate physical therapy intervention may be). The technology company could provide the physician group with necessary digital health technology that improves the physician group's ability to observe recovery and intervene, as necessary." However, the OIG final rule requires that the exchange of digital health technology by a limited technology participant is *not* conditioned on any recipient's exclusive use of, or minimum purchase of, any item or service manufactured, distributed, or sold by the limited technology participant.

The Stark Law final rule does not exclude such entities from qualifying as VBE participants under any exception for value-based arrangements. However, because the Stark Law is focused on prohibiting self-referrals by physicians, the new Stark Law exceptions for value-based arrangements will be of limited value to medical device and pharmaceutical companies.

USPTO Deferred-Fee Provisional Application Pilot Program for COVID-19 Related Inventions



In an effort to lend further support to the expedited development of COVID-19-related vaccines and therapeutics (*see* **Covid-19 Prioritized Examination Pilot Program**), the United States Patent and Trademark Office (USPTO) has implemented a deferred-fee provisional patent application pilot program whereby applicants filing under 35 U.S.C. 111(b) can elect to defer the $300.00 USD provisional filing fee ($150 for small entities; $75 for micro-entities) until the filing of a corresponding non-provisional application.

In order to be eligible for the deferred-fee pilot program:

1. the subject matter disclosed in the provisional application must be directed to a product or process related to COVID-19;
2. the product or process must have obtained, be pending, or will seek prior to marketing, Food and Drug Administration (FDA) approval for COVID-19 use;
3. the applicant must submit a technical disclosure, a provisional application coversheet, and a completed PTO/SB/452 form ("Certification and Request for COVID-19 Provisional patent Application Program"); and
4. the applicant must agree that the technical subject matter disclosed in the provisional application will be published on the USPTO website.

While insulated from being cited against an inventor's own later-filed corresponding non-provisional

application in the United States, the USPTO warns that special consideration should be taken by applicants seeking international patent protection since "[m]any foreign jurisdictions treat an inventor's public disclosure made within one year of filing as prior art against the inventor's own application unless that earlier disclosure is the subject of a proper priority claim in that jurisdiction."

The USPTO will accept certifications and requests to participate in the deferred-fee program until September 17, 2021, after which the program may be extended beyond that date and may be expanded to other technological areas beyond COVID-19 requiring rapid innovation.

Is Prescription Support Software Classified as a Regulated Medical Device in Europe?



...the essential criterion for being classified as a medical device is the software's medical objective...

Background

Relying on an unregulated app or piece of standalone software to provide a diagnosis or recommend treatment could have potentially life-threatening consequences. In June 2020, the UK's medical devices regulator, the Medicines and Healthcare Products Regulatory Agency (MHRA) updated its **guidance** to help software and app developers in the medical field identify whether their products should be regulated as medical devices.

In particular, the MHRA endorsed the European Court of Justice (CJEU) ruling of **Snitem v Philips France C-329/16** from December 2017. This case considered whether prescription support software which used patient-specific data to detect drug interactions and excessive doses, constituted a medical device.

The CJEU's Judgment

The CJEU held that the prescription support software was a medical device under EU law for the following reasons:

- the software cross-referenced patient-specific data with the medicines that the prescriber had contemplated prescribing;
- the software automatically provided the prescriber with an analysis intended to detect possible drug interactions and excessive dosages; and

- the manufacturer intended the software to be used for one of more medical objectives specified in Article 1(2)(a) of the **Medical Devices Directive 93/42/EEC** (MDD), which include the diagnosis, prevention, monitoring, treatment or alleviation of a disease.

The CJEU further held that it is irrelevant whether the software acts directly or indirectly on the human body. According to the court, the essential criterion for being classified as a medical device is the software's medical objective, examples of which are mentioned above.

Practical Implications

The MHRA guidance provides further certainty that prescription support software and other decision support software in the medical field may be classified as medical devices and thus need to comply with the requirements under the MDD.

As a final point, the MDD is due to be replaced by the Medical Devices Regulation on 26 May 2021. A key implication is that the risk classification of a significant proportion of existing medical device software could change which would mean manufacturers will soon need to obtain regulatory approval to market such software in the EU.