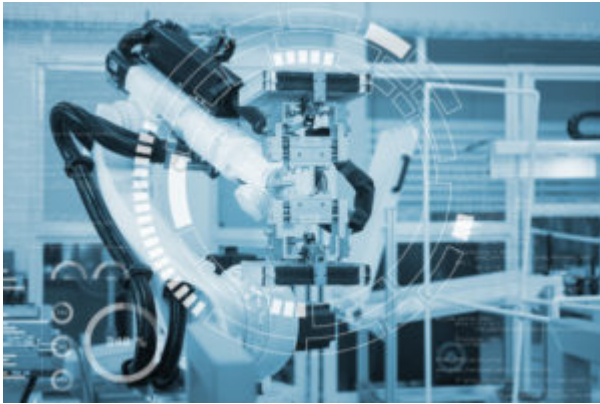


The European Commission Proposes to Extend the Transition Deadline in the EU Medical Device Regulation



... a major change to the Regulation is needed to prevent shortages of life-saving medical devices...

Background

On Friday 9 December 2022, the European Commission proposed to extend the transition deadline in the [Medical Device Regulation \(EU\) 2017/745 \(MDR\)](#). According to the European Commissioner for Health and Food Safety, Stella Kyriakides, a major change to the Regulation is needed to prevent shortages of life-saving medical devices, from implants and prosthetics to ventilators and pacemakers.

Medical devices in the EU are regulated under the MDR, and the MDR replaced the previous Medical Devices Directive 93/42/EEC (**MDD**) and the Active Implantable Medical Devices Directive 90/385/EEC (**AIMDD**) on 26 May 2021. Currently, medical devices can be placed on the EU market under a CE mark certificate issued under the MDD or AIMDD until 26 May 2024 (**Transition Deadline**). After the Transition Deadline, these products will require a CE mark certificate issued under the MDR so that they remain available on the EU market – a potentially costly and time-consuming process.

A broad range of stakeholders in the medtech sector consider the Transition Deadline to be unattainable. The pandemic, shortages of raw materials caused by the conflict in Ukraine and low Notified Body capacity have collectively put a strain on the ability for medical device manufacturers to meet the Transition Deadline. Without an extension to the Transition Deadline, it is anticipated that a significant number of medical device manufacturers would need to take their products off the EU market due to an inability to comply with the new requirements under the MDR within the required timeline.

Key Proposals

The European Commission has proposed the following legislative amendments:

- Extension of the Transition Deadline in the MDR based on the risk class of each device:
 - 26 May 2027 for Class III and Class IIb medical devices; and
 - 26 May 2028 for Class IIa and Class I medical devices.
- Extension of the validity of CE mark certificates issued under the MDD and AIMDD if needed for legal and practical reasons (e.g. to access markets outside of the EU that accept products

with a CE mark), provided that:

- the device does not present an unacceptable risk to health and safety;
 - the device has not undergone significant changes in design or intended purpose; and
 - the manufacturer has already undertaken the necessary steps to launch the CE mark certification process under the MDR (e.g. lodged an MDR application with a Notified Body by 26 May 2024).
- Elimination of the “sell-off” date under the MDR and under the [**In Vitro Diagnostic Medical Device Regulation \(EU\) 2017/746 \(IVDR\)**](#) to avoid safe medical devices and in vitro diagnostics (e.g. blood glucose meters) that are already on the EU market from having to be discarded by 27 May 2025.

Next Steps

The European Commission intends to provide these legislative amendments to the EU legislature for consideration at the beginning of 2023.

The European Commission also intends to undertake a comprehensive evaluation of the MDR by May 2027. The purpose of the evaluation is to identify structural problems with the MDR and potential medium and long-term solutions to these concerns.

As a final note, except for the elimination of the “sell-off” date, none of the proposed legislative amendments applies to in vitro diagnostics. Given that there are still few Notified Bodies under the IVDR, similar amendments might also be required for in vitro diagnostics in the near future.

Congress Expands Pathway for Drug & Device Manufacturers’ Pre-Approval Communication of Health Care Economic Information to Payors, Formularies, & Similar Entities



The legislation previously introduced as the [**Pre-Approval Information Exchange Act of 2022**](#) (“PIE Act”) was passed as part of Congress’s December 23, 2022 omnibus spending bill. Once signed into law, this legislation will amend the Federal Food, Drug, and Cosmetic Act’s (FDCA’s) provisions on misbranded drugs and devices to formally allow drug and medical device

manufacturers to proactively share investigational drug and device information, including health care economic information, with payors, health plans, formulary committees, and other similar entities *prior* to the clearance or approval of the drug or device or new use of the drug or device but with now-statutory strings attached.

The US Food and Drug Administration (FDA) has long had the authority to enforce against pre-approval *promotional* communications, and a pathway for pre-approval communication of health care economic information regarding the selection of drugs for coverage and reimbursement was enacted under the Food and Drug Administration Modernization Act of 1997. [Current guidance from FDA](#), finalized in 2018, expressly permits drug and device companies to provide some details about investigational products or investigational uses of marketed products to payors, formulary committees, and similar entities prior to approval or clearance of the product or its new use; however, for device companies this has come in the form of non-binding guidance that lacks a formal anchor in the statutory language. The inclusion of the legislation previously known as the PIE Act in the omnibus spending bill formally establishes a statutory pathway built on FDA's 2018 final guidance for both drug and medical device companies to engage in pre-market communications about health care economic information with payors, formulary committees, and similar entities.

Read the client alert [here](#).

[USPTO Announces Cancer Moonshot Expedited Examination Program](#)



The U.S. Patent and Trademark Office ("USPTO") published a Notice in the Federal Register announcing a new pilot program entitled, "Cancer Moonshot Expedited Examination Pilot Program" (the "Cancer Moonshot Program") (87 Fed. Reg. 75608 (December 9, 2022)) (the "Notice") to attempt to further accelerate innovation in the health and medical fields. Beginning on February 1, 2023, this new program will replace the Cancer Immunotherapy Pilot Program and expedite examination for a broader scope of technologies to prevent cancer and advance smoking cessation. The Cancer Moonshot Program is to support President Biden's recently renewed Cancer Moonshot initiative, which set a new goal of reducing cancer death rate by at least 50% over the next 25 years.

In contrast to the current Cancer Immunotherapy Pilot Program, which required the application to contain a claim to a method of treating a cancer using immunotherapy, the Cancer Moonshot Program covers a wider range of eligible technology areas. Under the new program, applications

must be in the field of oncology or smoking cessation and must contain at least one of the following method claims (collectively, the “eligible method claims”):

1. A method of treating or reducing the incidence of a cancer using an immunotherapeutic compound or composition (cancer immunotherapy related technology area);
2. A method of treating a cancer by targeting specific genetic markers or mutations using a specific pharmaceutical composition (personalized medicine related technology area);
3. A method of treating a rare or childhood cancer using a specific pharmaceutical composition (rare cancers related technology area);
4. A method of detecting or treating a cancer using a medical device specifically adapted to detect or treat the cancer (medical device related technology area);
5. A method of treating a cancer by administering a specific pharmaceutical composition wherein the method comprises a step to diagnose the cancer (diagnostic and treatment related technology area); and
6. A method of treating a nicotine dependency and promoting smoking cessation by administering a specific pharmaceutical composition (nicotine dependency and smoking cessation related technology area).

If the application contains “eligible” product or apparatus claims (i.e., claims to the immunotherapeutic compound or composition, the pharmaceutical composition, or the medical device used in an eligible method claim), the eligible method claims must depend from or be commensurate in scope with the eligible product or apparatus claims in the application (i.e., the eligible method claims must contain all of the limitations of the eligible product or apparatus claims).

The Notice details the requirements for petitions to make special under the Cancer Moonshot Program. For example, the application must be a nonprovisional utility patent application and contain no more than 3 independent and 20 total claims, with no multiple dependent claims. The claims must include at least one eligible method claim and a statement to that effect including that the application is limited to the field of oncology or smoking cessation. A statement must be filed indicating that special status was not previously granted for any reason for the application. In addition, a limitation exists on the number of times an inventor can file for special status under this program. Finally, a USPTO form must also be filed with the application, which form contains the necessary certifications for qualification to participate in the program.

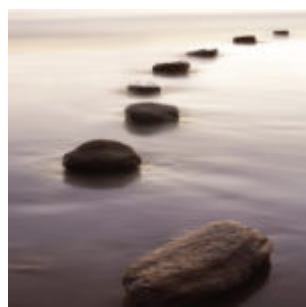
Upon granting of the petition, the application will be treated as special on an examiner’s docket and taken up out of turn for examination. The application will be accorded special status until a first Office action, which may be a restriction requirement. After the first Office action, the application will no longer be entitled to special status and will be taken up in a normal course on the examiner’s docket. That is, after the first Office action, the application will undergo regular examination similar to all other applications.

The Notice indicates that the USPTO will periodically evaluate the Cancer Moonshot Program to determine whether and to what extent its coverage should be changed.

Let’s hope that this incentivization program provides a real impact on accelerating innovation in

developing new treatments for cancer. And if interested in participating in the program, please contact a Goodwin patent lawyer.

USPTO and FDA Continue to Focus on Patent Quality in the Pharmaceutical Industry



After a recent reminder from the U.S. Patent and Trademark Office (USPTO) regarding the duties of disclosure and reasonable inquiry during examination of a patent application and a Request for Comments (RFC) on the USPTO initiatives to ensure “robustness and reliability” of patent rights,[1] the Director of the U.S. Patent and Trademark Office published a third notice in less than four months. The latest notice is in conjunction with the Food and Drug Administration (FDA) to further the discussion surrounding the patent practices of the pharmaceutical industry ([87 Fed. Reg. 67019](#) (November 7, 2022)). Specifically, the notice is of a public listening session and request for comments (PLS/RFC).

Against the backdrop of President Biden’s Competition Executive Order (EO) that calls for action “to help ensure that the patent system, while incentivizing innovation, does not unjustifiably delay generic drug or biosimilar competition beyond that reasonably contemplated by applicable law,” as well as Congressional and public interest in this goal, the stated purpose of the present notice of the PLS/RFC is to obtain public input for areas of joint USPTO-FDA collaboration and engagement with respect to the pharmaceutical industry to promote greater access to medicines for American families.

In particular, the USPTO and FDA are seeking feedback from a broad group of stakeholders, most notably, patients and their caregivers, patient advocates, representatives from regulated industry, including companies that sell branded medicines, generic drugs and biosimilars, healthcare organizations, payers and insurers, academic institutions, public interest groups, and the general public.

The background of the notice of the PLS/RFC describes the response to the EO and details certain communications between the USPTO and the FDA in furtherance of its objectives. More specifically, in a letter from the USPTO to the FDA, initiatives for collaboration were outlined including exploring joint USPTO-FDA public engagements, providing examiners with training on publicly available FDA resources, exploring consistency in representations made to the USPTO and the FDA, revisiting patent term extension (PTE) practice, exploring the policies surrounding the use of “skinny labels,” and being open to discussing “patent thickets,” “evergreening,” and “product hopping.”

Further, in the current notice, the USPTO states in a footnote that this collaborative PLS/RFC is in parallel with the USPTO’s initial RFC. The initial RFC included new USPTO initiatives to advance the EO; such initiatives include seeking input on enhancing processes for information disclosure

statements and the identification of key prior art, considering applying greater scrutiny to continuation patent applications and use of declaratory evidence during patent prosecution, revisiting terminal disclaimer practice and procedures for third party input during prosecution, and conducting a comparative analysis of the prosecution and grant of “pharmaceutical and biological patents” in the United States versus other countries.

Although the USPTO notice on disclosure requirements and the initial RFC include all technologies, it is clear that the focus of the USPTO/FDA’s inquiries are related to the pharmaceutical and biologics industries.

More specifically, with respect to the PLS/RFC, its inquiries include considering what FDA resources may be available to USPTO examiners to assess patentability, e.g., determining whether inconsistent statements were made to the USPTO and the FDA, using AIA proceedings to address the patentability of claims in pharmaceutical and biotechnological patents, revisiting PTE practices, understanding “skinny label” practice, and generally promoting greater availability of generic products. The PLS/RFC also seeks input on the questions posed in the USPTO letter to the FDA mentioned above.

The in-person PLS at the USPTO is scheduled for January 19, 2023, from 10 am to 5 pm (ET), for which preregistration is needed to speak. Written comments to the PLS/RFC will be accepted until February 6, 2023, with the comments to the initial RFC of the USPTO extended until February 1, 2023.

Stakeholders are encouraged to participate and we will monitor how the USPTO and the FDA respond to these hotly debated topics that impact almost every American.

[1] See [87 FR 45764](#) (July 29, 2022) and [87 FR 60130](#) (October 4, 2022), respectively. See also [USPTO Publishes Notice Calling Out Pharmaceutical Industry](#), Goodwin Life Sciences Perspective blog, July 29, 2022; and [USPTO Doubles Down Calling Out Pharmaceutical Industry](#), Goodwin Life Sciences Perspective blog, October 19, 2022, respectively.

[Avoiding Misbranding: Words Matter When Describing the Regulatory Status of 510\(k\) Cleared Devices and Registered Device Establishments](#)



When it comes to discussing medical devices regulated by the U.S. Food and Drug Administration (FDA), words such as “approved” and “cleared” cannot be used interchangeably as these terms carry a particular meaning. Similarly, creating an impression of approval of a device establishment or its devices because the establishment is registered with FDA also is prohibited. Long-standing regulatory provisions, [21 C.F.R. § 807.97](#) and [21 C.F.R. § 807.39](#), set forth, respectively, the FDA’s position that approval and clearance are not interchangeable and that device establishment registration does not denote approval of the establishment or its devices. Importantly, these provisions also highlight the consequences to industry for misusing terms when discussing the regulatory status of a device or a device establishment.

When seeking to market a new device for which a premarket notification must be submitted to the FDA demonstrating that the device to be marketed is substantially equivalent to a legally marketed device, the submitter must obtain an order of substantial equivalence from the FDA, which is commonly referred to as a 510(k) *clearance*. Conversely, to market a new device for which a premarket approval application must be submitted to the FDA, the applicant must obtain FDA’s *approval* of the application. While FDA review and FDA action occur for both types of medical devices, the outcomes of clearance and approval are distinctly different and carry legal consequences. Specifically, 21 C.F.R. § 807.97 states that “[a]ny representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.” Additionally, 21 C.F.R. § 807.39 states that “[a]ny representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding.”

We researched Warning Letters in [FDA’s Warning Letter Database](#) and found that FDA issued four Warning Letters citing violations of § 807.97 since 2017 and thirteen Warning Letters citing violations of § 807.39 since 2017.

Many of the representations that FDA found to be misleading under § 807.97 were straightforward violations, such as language on product websites stating that cleared devices are “FDA approved,” or listings of device clearances under the heading “FDA Approvals.” In one instance, FDA found the website to be misleading under both § 807.39 and § 807.97 because the company claimed the device had been cleared by the FDA, when in fact it was marketing a 510(k) exempt device for an indication that would require a de novo authorization which the company had not obtained, and the website claimed the company maintained an active listing, which was hyperlinked to the company’s FDA Establishment Registration and Device Listing for only the 510(k) exempt device.

In response to the COVID-19 public health emergency, FDA issued twelve Warning Letters related to representations regarding masks and antibody tests that were found to be misleading under § 807.39. In virtually all of these instances, company websites displayed unofficial “certificates of FDA registration” issued by third parties which claimed to certify that the manufacturer had completed FDA Establishment Registration and Device Listing. These certificates often incorporated

unauthorized reproductions of FDA's logo and motifs of the U.S. flag, giving the impression of official government documents. FDA consistently found the display of these certificates to be misleading, even when they included ostensible "disclaimer" language stating that the certificates did not denote FDA endorsement or approval. FDA repeatedly found that these disclaimers did not adequately limit or otherwise mitigate the misleading impression of the certificates because they were phrased, designed, and placed in a manner where they could be easily overlooked.

These Warning Letters present a cautionary tale to all sponsors intending to market new medical devices. While sponsors may be tempted to claim their devices are approved by the FDA following the agency's review of a premarket notification or upon completion of FDA Establishment Registration and Device Listing, § 807.97 and § 807.39 make clear that such claims will constitute misbranding. Sponsors can avoid § 807.97- and § 807.39-related Warning Letters and associated liability by carefully reviewing all of the language on their marketing materials and websites to ensure that none of their representations create the impression of official approval based on reference to a premarket notification submission or establishment registration.

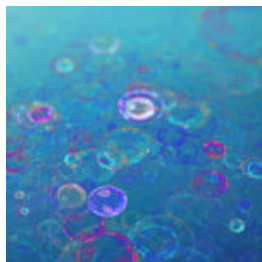
Five Key Regulatory Considerations for Virtual Ketamine Clinics



The off-label use of ketamine to treat anxiety, depression, and other behavioral health disorders —coupled with the COVID-19 telehealth era—has spurred the opening of virtual ketamine clinics nationwide. Some clinics offer a full suite of health care services, including telehealth visits, prescribing, pharmacy dispensing, and counseling services, while others are focused on more niche areas like group coaching sessions. In the wake of public reports detailing investigations into a number of digital health companies prescribing controlled substances, it is more important than ever to ensure your business model complies with the various regimes regulating the use of ketamine to treat behavioral health issues.

Read the client alert [here](#).

FDA Announces Total Product Life Cycle Advisory Program (TAP) Pilot



The U.S. Food and Drug Administration's ("FDA" or "the Agency") Center for Devices and Radiological Health ("CDRH") recently announced the launch of its Total Product Life Cycle Advisory Program ("TAP") Pilot. The first phase of this voluntary initiative, called TAP Pilot Soft Launch, will be conducted during fiscal year ("FY") 2023 with enrollment beginning on January 1, 2023.

The Agency committed to establishing the TAP Pilot as part of the MDUFA V reauthorization, and the Agency's long-term vision for TAP is "to help spur more rapid development and more rapid and widespread patient access to safe, effective, high-quality medical devices of public health importance." As part of the TAP Pilot, the FDA will provide strategic engagement for such devices by:

- Improving participants' experiences with the FDA by providing for more timely premarket interactions
- Enhancing the experience of all participants throughout the device development and review process, including FDA staff
- Facilitating improved strategic decision-making during device development, including earlier identification, assessment, and mitigation of device development risk
- Facilitating regular and solutions-focused engagement early in device development between FDA review teams, participants, and other stakeholders, such as patients, providers, and payers
- Collaborating to better align expectations regarding evidence generation, improve submission quality, and improve the efficiency of the premarket review process

Read client alert [here](#).

FDA Issues Final Clinical Decision Support Software Guidance



On September 28, 2022, the U.S. Food and Drug Administration ("FDA" or "the Agency") issued its long-awaited final guidance, "Clinical Decision Support Software" (the "CDS Guidance"). The CDS Guidance follows the Agency's September 2019 draft guidance of the same name (the "Draft Guidance") and seeks to clarify several key concepts for determining whether clinical decision support ("CDS") software is a medical device.

Specifically, the CDS Guidance provides the Agency's interpretation of the four criteria established by the 21st Century Cures Act for determining whether a decision support software function is excluded from the definition of a device (i.e., is considered "Non-Device CDS"). A software function must meet all of the following four criteria to be considered Non-Device CDS:

1. Not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device ("IVD") or a pattern or signal from a signal acquisition system
2. Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);
3. Intended for the purpose of supporting or providing recommendations to a health care professional ("HCP") about prevention, diagnosis, or treatment of a disease or condition
4. Intended for the purpose of enabling such HCP to independently review the basis for the recommendations that such software presents so that it is not the intent that the HCP rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient

Software functions that *do not* meet all four criteria are considered device functions subject to FDA oversight. Notable updates to FDA's interpretation of the four criteria include the following.

Read the Goodwin insight [here](#).

[USPTO Doubles Down Calling Out Pharmaceutical Industry](#)



The new Director of the U.S. Patent and Trademark Office (USPTO), Katherine Vidal, published a stern reminder regarding the duties of disclosure and reasonable inquiry during examination of a patent application, including reexamination, reissue, and proceedings before the Patent Trial and Appeal Board (PTAB) (87 FR 45764 (July 29, 2022)). The justification was to provide examiners and judges with all the material information needed to decide on patentability of a claimed invention. According to the USPTO, more robust and reliable patents should result, which is better for the public. [See USPTO Publishes Notice Calling Out Pharmaceutical Industry](#), Goodwin Life Sciences Perspective blog, August 1, 2022.

The USPTO now published a Request for Comments (RFC) (87 FR 60130 (October 4, 2022)) on USPTO initiatives to ensure "robustness and reliability" of patent rights, the new buzz words for increased patent quality. Again, the pharmaceutical industry appears to be the main target of the new initiatives. In the background section is President Biden's Competition Executive Order (EO) that calls for action "to help ensure that the patent system, while incentivizing innovation, does not unjustifiably delay generic drug or biosimilar competition beyond that reasonably contemplated by

applicable law.” The RFC also references the Food and Drug Administration and USPTO interactions and communications to help promote the EO.

In particular, the new initiatives for “robust and reliable” patents are primarily directed to preventing what’s been termed, “patent thickets,” which has been defined by Senators Leahy, Blumenthal, Klobuchar, Cornyn, Collins and Braun as a “large number of patents that cover a single product or minor variations on a single product.” According to the Senators, patent thickets impede the generic drug industry to the detriment of the U.S. public.

Included in the new USPTO initiatives to execute the EO are more time and resources to examine patent applications, enhanced processes for information disclosure statements and the identification of key prior art, consideration of applying greater scrutiny to continuation patent applications and use of declaratory evidence during patent prosecution, revisiting terminal disclaimer practice and procedures for third party input during prosecution, and a comparative analysis of the prosecution and grant of “pharmaceutical and biological patents” in the United States versus other countries.

The stated primary purpose of this RFC is to solicit comments from the public on these initiatives, the latter of which is specific to the pharmaceutical industry. Of note, though, the specific topics and initiatives currently being addressed in the RFC are prior art searching, e.g., databases of non-patent literature, support for patent claims in continuation patent applications including priority dates, request for continued examination (RCE) practice, and restriction, divisional, and terminal disclaimer practices.

The RFC includes a list of eleven questions. The first five, some with many subparts, address the USPTO topics and initiatives discussed immediately above. The final six questions are directly from a letter from the Senators to the USPTO. These latter questions are quite enlightening as to what’s in the minds of the Senators and their possible solutions to their perceived problems with the U.S. patent system.

More specifically, the Senators question terminal disclaimer practice, suggesting eliminating it to prohibit patents that are obvious variants. Another question suggests that patents terminally disclaimed over each other should stand or fall together with respect to their validity because they are all obvious variants of each other. Other questions lean towards higher scrutiny and examination of continuation patent applications including limiting the time frame when such applications can be filed and increasing the fees for such filings.

Although the specific questions posed do not single out patents of the pharmaceutical industry nor include a comparison of such patents to non-U.S. counterpart patents, the incentive for the RFC, which typically precedes a notice of proposed rulemaking, seems to signal an attempt to change the current patent practices of the pharmaceutical industry.

In sum, similar to the USPTO Notice on disclosure requirements, although all technologies are included, the RFC appears to be directed most specifically to brand name pharmaceutical companies. Is the RFC another shot over the bow of the brand name pharmaceutical companies’ patent filing and prosecution strategies? Is this more signaling of the beginning of higher scrutiny for their patent applications and the “patent thickets” they create? If so, will such scrutiny permit generics to enter the marketplace earlier, to meet the Administration’s objectives? Again, only time will tell.

Significant Drug Pricing Reform Measures in the Inflation Reduction Act of 2022



On August 16, President Biden signed the Inflation Reduction Act of 2022 into law,^{[\[1\]](#)} which includes some of the most significant drug pricing-related changes since the passage of the Medicare Prescription Drug Improvement and Modernization Act of 2003.

The healthcare-related portions of the law introduce many important changes, most notably allowing the Medicare program to negotiate with pharmaceutical companies for reduced prescription drug prices under Medicare Part B and Medicare Part D (commonly known as the Prescription Drug Benefit for America's senior population) for certain single-source drugs, or rather those drugs and biologicals without generic or biosimilar competitors. The law will also require drug makers to pay the government a rebate for any drug whose price increases faster than the pace of inflation. It also modifies several aspects of the Part D benefit to cap Medicare beneficiaries' out-of-pocket costs.

[Heath Ingram](#), [Matt Wetzel](#) and [Roger Cohen](#) provide a high-level summary of these provisions and other important considerations in this [client alert](#).