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HALT Fentanyl Act: Clarification of the Campus DEA Research Registration

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On July 16, 2025, President Trump signed into law the Halt All Lethal Trafficking of Fentanyl Act (HALT Fentanyl Act or the Act), which significantly reformed the 1970 Controlled Substances Act (CSA).[1] The HALT Fentanyl Act permanently reclassifies "fentanyl-related substances" as Schedule I controlled substances. Moreover, the Act simplifies Drug Enforcement Administration (DEA) research registration requirements in several ways, including (1) streamlining research registration processes for Schedule I or II controlled substances registrants performing research involving Schedule I controlled substances under active investigational new drug applications (INDs) or conducted or funded by certain federal agencies, (2) allowing agents or employees of a research institution to conduct research with a controlled substance without separately registering if another agent or employee of that institution is registered to conduct research with a controlled substance in the same schedule, and (3) expanding the ability of persons registered to perform research on a controlled substance to perform certain manufacturing activities coincident to that research without needing to obtain a manufacturing registration.

Perhaps most important for universities, academic medical centers, and research institutions, the Act allows a DEA research registrant (which could include a university, academic medical center, or research institution or a unit, department, or group of such an entity) to conduct research with Schedule II to V controlled substances at different sites under a single DEA research registration if the sites are in the same city or county and under the control of the same institution, organization, or agency. This confirms the legality of the "campus registration" model of DEA Schedule II to V research registration which has been permitted by DEA on a case by case basis. The campus registration model

permits an institution to rely on a single institutional DEA research registration for all research sites across a contiguous campus operated by an institution and obviates the need for institutions to apply for separate DEA research registrations for every room in which Schedule II to V substances are stored or dispensed. The campus registration model should greatly reduce aggregate administrative burden for universities, academic medical centers, and research institutions, simplify ordering and disposal, and significantly reduce the risk of diversion.

Separate Registrations for Separate Location Rule – Location Limited to Room Interpretation

The CSA states that "[a] separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances[2] or list I chemicals."[3] Likewise, the relevant implementing DEA regulation labels this the "separate registrations for separate locations" rule and states: "A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person."[4] Violations of the CSA including violations of registration requirements can lead to significant civil monetary penalties including $25,000 per violation for distributing or dispensing a controlled substance not authorized by the person's registration and $10,000 per violation for failing to make, keep or furnish requisite records.[5] Although "principal place of business" seems like it should encompass a campus of a university, academic medical center, or research institution, many DEA field offices narrowly interpreted the term to be limited not just to a single building but to a single room in a building. Thus, under this interpretation, for example, a researcher storing or dispensing Schedule II to V controlled substances in a room on the 7th floor of a building as well as in a different room on the same floor of the same building would need two separate DEA research registrations. This interpretation meant that, for a campus of a university, academic medical center, or research institution, researchers would need to apply for hundreds or thousands of individual DEA research registrations for each room in which Schedule II to V controlled substances were stored overnight or dispensed.

The interpretation also meant that Schedule II to V controlled substances used for research could only be received at each of the registered locations rather than a centralized receipt location. This increased the risk of diversion because controlled substances orders were delivered directly to individual laboratories rather than to a centralized receipt location run by an experienced campus-wide controlled substances administrator. Similarly, if a laboratory wanted to dispose of such substances by sending them to a reverse distributor, the reverse distributor had to retrieve the substances from the laboratory where the process would be handled by laboratory staff, instead of a centralized retrieval location run by an experienced controlled substances administrator.

Separate Registrations for Separate Location Rule – Campus Registration Interpretation

Despite this narrow interpretation, for many years, several DEA offices, including the DEA Diversion Control Division at DEA headquarters, have supported a campus registration model for Schedule II to V research. These DEA offices allowed universities, academic medical centers, or research institutions

(or units or departments of such entities) to perform research across different rooms and buildings located in a contiguous campus under a single DEA research registration. This model allowed institutions to order and receive controlled substances at a centralized receipt location and then deliver the controlled substances to different laboratories in different buildings. The intra-campus delivery would be between locations on a single registration and thus would not constitute a "distribution" requiring a separate distribution registration or compliance with the "5 percent rule,"[6] which limits a practitioner to distributing 5% of total controlled substances dispensed in a calendar year.

In February 2019, DEA's nationwide Diversion Control Division ran nationwide trainings[7] for researchers in which it acknowledged the campus registration model and discussed plans to expand it. One of the future plans involved adding or deleting research sites on the DEA's website. The Diversion Control Division noted that campus registration was not an exemption but rather an inclusion of specific locations under a single DEA registration. The Division noted that the model pertained to Schedule II to V controlled substances rather than Schedule I controlled substances. The Division stated that it reviewed requests on a case-by-case basis, considering factors such as whether the company was operating a single business activity in more than one building, how close the buildings were to one another, whether conferral of a campus registration would diminish the security of the controlled substances within the registrant's possession or control and whether there were any field on-site inspection concerns.

In 2021, the DEA acknowledged that it considered campus registration requests on a case by case basis. However, due to the absence of applicable regulations, DEA announced that it planned to issue a proposed rule.[8] Despite this intention, however, proposed regulations have not been published to date.

HALT Fentanyl Act Support of Campus Registration Interpretation

With the HALT Fentanyl Act, the inconsistently-endorsed campus registration model is now more clearly authorized by statute. The Act permits an additional exception to the requirement in 21 U.S.C. § 822(e)(1) that separate locations require separate registrations. In particular, it modifies 21 U.S.C § 822(e)(4) to permit a person with a DEA research registration under Section 823(g) to conduct research at different research sites under a single registration if all research sites are in the same city or county and under the control of the same institution, organization or agency. The research registrant need only first notify DEA of each site where the research will be conducted or the controlled substances will be stored or administered.

Under 21 U.S.C. § 823(g), a "practitioner" is allowed to obtain a registration to dispense or conduct research for Schedule II-V controlled substances and under 21 U.S.C § 802, the definition of "practitioner" is not limited to individuals but includes hospitals, pharmacies, and other "persons." Although "person" is not defined in the CSA, it is defined by DEA at 21 C.F.R § 1300.01 as "any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity." An institution such as a university, academic medical center, or research institution constitutes a legal entity, and thus is able to qualify as a practitioner or person and can apply in its own name for a DEA research registration.

Comments on Forthcoming Regulations for Universities, AMCs and Research Institutions

While the Act was effective immediately upon enactment, it contemplates an interim final rule to be issued within six months as well as an opportunity to comment and to request a hearing. The Act also states that DEA may issue regulations on the Act's provision permitting different research sites under a single DEA Schedule II to V research registration including:

i. the manner in which controlled substances may be delivered to the research sites;
ii. the storage and security of controlled substances at the research sites;
iii. the maintenance of records for the research sites; and
iv. any other matters necessary to ensure effective controls against diversion at the research sites.

Universities, academic medical centers, and research institutions should be prepared to comment on the interim final rule and/or regulations regarding single registration for different research sites, including the following:

1. A "research site" under Section 822(e)(4) should not be limited to laboratories where Schedule II to V controlled substances are dispensed or stored for dispensing. A "research site" should also include a centralized location where Schedule II to V controlled substances can be received after ordering or stored in preparation for disposal. Deliveries between the centralized location and laboratories in which such substances will be stored or dispensed (or between the laboratories themselves) should not constitute "distributions" within the meaning of the CSA.

2. The Act envisions a simple method for adding new research sites under the single registration. The institution must simply provide advance notice to the DEA of the site where the research will be conducted or the controlled substance will be stored or administered. DEA should follow Congress' direction in providing an expedited, simple method of adding and deleting research sites. DEA should follow the Diversion Control Division's earlier proposal to add or delete research sites from a campus registration on-line. DEA should not, for example, require physical inspections or blueprints for all sites especially if the institution has provided policies and procedures outlining security safeguards consistent with DEA regulations.[9]

3. In light of Congress' encouragement for DEA to consider diversion risk when implementing the single regulation model, institutions should indicate their willingness to limit institutional registrations to a contiguous campus. DEA is already familiar with operating the campus registration model, which, as noted above, has been permitted on a case by case basis. Limiting institutional registrations to a campus registration would reduce administrative burden while still protecting against diversion. Institutions should determine whether there are any situations in which they would benefit from an institutional registration that included an entire county rather than a contiguous campus. One possible example would be off-campus remote field offices. Institutions may wish to contend that small amounts of Schedule II to V controlled substances should be permitted to be stored or dispensed at these off-campus field offices in the same city or county as a campus registration, given the low risk of diversion due to the low volume of such substances and the remoteness of the locations.

4. Institutions should also ask DEA to permit single, institutional Schedule II to V controlled substances research registrations by institutional unit, department, or groups of researchers. A single registration for an entire campus carries it with it risk if there are ever issues concerning that registration. Sanctions against a single campus registration could lead to an entire campus's Schedule II to V controlled substances research being stopped or delayed. It may also simpler for an institution to ensure compliant documentation (e.g., logs, biennial inventories, DEA Form 222s, orders and deliveries) for, and for DEA to inspect, such smaller groups of researchers. For these reasons, DEA should permit, and institutions should consider, applying for single research registrations that encompass more than an individual researcher but less than an entire campus, such as a unit, department, or group.

Confirmation or Conversion to Campus Registration Prior to Issuance of Regulations

In addition to the comments on the upcoming interim final rule and/or regulations, institutions currently operating under campus research registrations should contact their local DEA field office to streamline the operation of their campus research registration prior to issuance of the interim final rule and/or regulations. This would include, for example, permitting the on-line addition or deletion of research sites by way of advance notice only and allowing a centralized receipt/disposal location. Given that DEA campus registration regulations were not issued for four years despite DEA's notice of intent to do so in 2021, clarification of the campus research registration model under the Act's changes should not be similarly delayed pending issuance of the interim final rule and/or regulations.

Institutions acting under multiple individual research registrations rather than a single campus registration should consider contacting their local DEA field office to discuss how to convert to a campus registration prior to issuance of the interim final rule and/or regulations. Some negative factors such institutions may wish to consider when deciding whether to convert to campus registration include: (1) immediate upfront costs if they have to hire a campus-wide controlled substances administrator and transition to a campus registration model and a centralized receipt location, and (2) resistance from individual researchers from closer institutional oversight. Some factors favoring adoption of the campus registration model include (1) reduction in diversion risk, (2) decrease in administrative burden in the long term, and (3) savings for those institutions that are non-exempt from not being required to pay the $296 application fee for each individual research registration.

Extension of Campus Registration to Schedule II to V DEA Hospital/Clinic Clinical Registration

In addition to the foregoing, hospitals and clinics should also encourage their federal government relations representatives and their associations to advocate that hospitals and clinics be permitted to use a similar "campus registration" model for clinical use of Schedule II to V controlled substances. The "separate registrations for separate locations" rule in 21 U.S.C § 822(e)(1) not only applies to research use of controlled substances but also applies to clinical use of controlled substances by hospitals and clinics. There is no reason why a similar exception should not be made for hospitals and clinics to be permitted to store or dispense these controlled substances at different clinical sites on the same

contiguous campus under a single hospital or clinic DEA registration. Indeed, during the pandemic, DEA permitted a temporary waiver of the "separate registrations for separate locations rule" to allow handling of controlled substances at remote, affiliated satellite/hospital locations under the hospital or clinic's DEA registration.[10] Although the waiver has since been rescinded, DEA made clear that it had historically permitted a clinical "campus registration" model for hospital and clinic locations on the same contiguous campus: "DEA has long allowed hospitals/clinics with multiple buildings to handle controlled substances under a single registration, provided all such activity occurs on a single, contiguous campus." Now that the Act permits different research sites in the same city or county controlled by the same institution, organization, or agency, a similar statutory exception should be made to support the "campus registration" model for hospitals and clinics to handle Schedule II to V controlled substances for clinical purposes. This expansion is particularly justifiable as to hospitals and clinics since state licensure requirements and joint accreditation standards act as additional safeguards against diversion.

Conclusion

The HALT Fentanyl Act resolves the inconsistently applied "campus registration" Schedule II to V controlled substances research registration model and confirms that universities, academic medical centers, and research institutions can consolidate their Schedule II to V controlled substance research sites in the same city or county under single campus registrations or registrations by unit, department, or group. Uniform adoption of this model should ease administrative load, enhance oversight, and reduce the risk of diversion. Ongoing engagement during the regulatory process will be crucial to ensure that the DEA administers this model in the simplified manner mandated by the Act without sacrificing robust diversion controls.

[1] H.R.27 - 119th Congress (2025-2026): HALT Fentanyl Act | Congress.gov | Library of Congress.

[2] "The term 'controlled substance' means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986." *Id.* § 802(6).

[3] *See* 21 U.S.C § 822(e)(1).

[4] 21 C.F.R § 1301.12(a).

[5] 21 U.S.C. § 842(a)(2), (a)(5) and (c)(1).

[6] 21 C.F.R. § 1307.11.

[7] https://www.deadiversion.usdoj.gov/mtgs/researcher_train/conf_2019/feb_2019/wingert.pdf.

[8] https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202110&RIN=1117-AB67#:~:text=The%20Drug%20Enforcement%20Administration%20%28DEA%29%20currently%20has%2(

[9] *See* 21 C.F.R § 1301.75.

[10] RESCINDED_(DEA-DC-028)(DEA084)_Hospital_Clinic_Registration_Exception_(final).pdf.

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