

## DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services  
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**Subject: Guidance on direct data entry (DDE) and use of automated tools for entering data;  
45 Code of Federal Regulations (C.F.R.) § 162.103 and § 162.923(b)**

The Office of Burden Reduction and Health Informatics (OBRHI) National Standards Group (NSG), on behalf of the Department of Health and Human Services (HHS), is issuing this guidance to clarify the definition of direct data entry at 45 CFR § 162.103 and the direct data entry exception at 45 CFR § 162.923(b).

### **Issue**

Several covered entities have submitted questions to the NSG regarding the direct data entry (DDE) exception at 45 CFR § 162.923(b). Some health care providers use automation software tools to expedite data entry into a health plan's DDE website or, in some cases, cause data to be entered into such systems without human intervention. Some automation software is known colloquially as "screen scraping." HIPAA covered entities have asked whether health care providers' use of various forms of automation software meets the DDE exception.

### **Background**

Several regulatory definitions and provisions are central to understanding the issue:

Section 45 CFR 160.103 defines a health care provider as "a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business."

DDE is defined at 45 CFR § 162.103 as "the direct entry of data (for example, using dumb terminals or web browsers) that is immediately transmitted into a health plan's computer."

With respect to conducting electronic transactions, 45 CFR § 162.923 sets forth the requirements for covered entities. Section 162.923(a) is captioned "General rule," and provides that "[e]xcept as otherwise provided in this part, if a covered entity conducts, with another covered entity that is required to comply with a transaction standard adopted under this part (or within the same covered entity), using electronic media, a transaction for which the Secretary has adopted a standard under this part, the covered entity must conduct the transaction as a standard transaction."

For health care providers, 45 CFR § 162.923(b) provides an exception for DDE transactions that states “[a] health care provider electing to use direct data entry offered by a health plan to conduct a transaction for which a standard has been adopted under this part must use the applicable data content and data condition requirements of the standard when conducting the transaction. The health care provider is not required to use the format requirements of the standard.”

The 2000 final rule titled *Health Insurance Reform: Standards for Electronic Transactions* ([65 FR 50312](#) at 50315) established the general rule and DDE exception. The proposed rule of the same name, published at [63 FR 25272](#) (May 7, 1998), did not mention DDE, though it spoke to a similar concept, proposing that “[e]ntities that offer on-line interactive transmission must comply with the standards. The HyperText Markup Language (HTML) interaction between a server and a browser by which the data elements of a transaction are solicited from a user would not have to use the standards, although the data content must be equal to that required for the standard.”

The final rule’s preamble presented a comment (representing multiple commenters) and HHS response in this regard. Several commenters suggested that HHS take a bifurcated view of electronic transmissions whereby “computer to computer without human interaction” transmissions would be subject to HIPAA standards, whereas “person to computer” transmissions, of which there could be various types, would be considered supplemental to, and not have to comply with, the HIPAA standards, though data content would still have to be compliant with the standards. Other commenters questioned whether health plans are required to support “person to computer” methods, and suggested that HHS except HTML from the standards only where web browsers are used, without “plug-ins or programmable extensions,” which are software applications that add additional capabilities to programs such as web browsers.

We said in the final rule that, in light of the many comments and developments in the industry, and contrary to the exception from the standards that we had proposed, we “will recognize that there are certain transmission modes in which use of the format portion of the standard is inappropriate. However, the transaction must conform to the data content portion of the standard,” though we continued by saying “[i]f the data is directly entered into a system that is outside of the health plan’s system, to be transmitted later to the health plan, the transaction must be sent using the full standard (format and content).”

## **Analysis**

In considering this issue anew, we note the following:

The definition of DDE at 45 CFR § 162.103 does not require direct entry of data by a human being. The phrase “the direct entry of data” as it appears in the context of the definition makes no mention of the method of data entry. In addition, although it was discussed in the preamble to *Health Insurance Reform: Standards for Electronic Transactions* final rule, the rule included no explicit restrictions on the method of data entry. Therefore, we also do not find support in the preamble of the final rule for any prohibition of software automation in the definition of DDE.

Next, we consider both the language of the definition of health care provider at 45 CFR § 160.103 as well as the language of the DDE exception at 45 CFR § 162.923(b). We first note that the exception for DDE applies to all health care providers. The definition of health care provider includes both individuals and organizations. As such, we could not consider the “health care providers” referenced at 45 CFR § 162.923(b) to only refer to a person. Rather, the exception applies to both people and organizations that meet the definition for health care provider and therefore cannot be interpreted to mean that only a person may conduct a DDE transaction under the exception, organizations may do so as well.

Further, we note that 45 CFR § 162.923(b) does include some restrictions on the use of DDE. Specifically, a health care provider must “use the applicable data content and data condition requirements of the standard when conducting the transaction.” No additional restrictions or limits on health plans or health care providers that utilize DDE appear in 45 CFR § 162.923(b). As we have already noted, several possible additional restrictions were discussed, but not included in the final rule. Because the rule includes some explicit restrictions on the use of DDE, but makes no restrictions on the method of data entry for DDE as discussed in the preamble to the final rule, we conclude that no prohibitions on the use of software automation was intended in 45 CFR § 162.923(b).

In conclusion, we do not consider the definition of DDE at 45 CFR § 162.103 to prohibit the use of software tools that assist or automate the entry of data, nor does the exception for the use of DDE at 45 CFR § 162.923(b) prohibit the use of such tools.

Finally, we note that health plans are not required to provide DDE by 45 CFR § 162.923(b). DDE systems are available at the discretion of health plans that voluntarily elect to provide them. We offer no comment on private contractual arrangements or trading partner agreements that may limit or alter the availability of DDE solutions or automation tools.

### **Additional Information**

Should you have questions about this guidance, send inquiries to [AdministrativeSimplification@cms.hhs.gov](mailto:AdministrativeSimplification@cms.hhs.gov) with the subject line: HIPAA Transaction Exception Question. Questions on other topics related to the adopted standards or operating rules may be sent to this same e-mail address. For more information, visit the CMS Administrative Simplification website at [go.cms.gov/AdminSimp](http://go.cms.gov/AdminSimp). For the latest news about Administrative Simplification, [sign up for Email Updates](#).

Sincerely,

Christine  
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Date: 2021.06.24 12:01:28 -0400

Christine Gerhardt  
Director  
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