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Standards in Law

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INTRODUCTION

A good lawyer prepares fastidiously for their practice of law, whether it be as a litigator in the courtroom or as a drafter of contractual agreements. And a good lawyer begins their career in law school. Because standards intersect many areas of legal study, from intellectual property and technology law to business and corporate law, teaching standards literacy to law students is an essential component of today's legal education. As discussed in previous chapters, standards developing organizations (SDOs) operate across industries, and standards are implemented by both private and governmental organizations.

Law schools in the United States have not traditionally focused on standards education as an element of the curriculum, but this is changing with the addition of coursework and the creation of supplemental educational materials by leading institutions, such as the University of Pennsylvania Carey Law School [1–2]. This chapter will provide an overview of the intersection between standards and two areas of U.S. law: *administrative law* and *intellectual property and technology law.*

Administrative Law

Administrative law is the study of governmental agencies, which are found on the federal and state levels. Agencies are delegated powers by Congress or state legislatures that permit them to administer, interpret, and enforce laws [3]. Of particular importance to the discussion is the role of administrative agencies in the rulemaking process. The U.S. rulemaking process, as illustrated in Figure 12.1, is a complicated procedure in which an agency promulgates binding law [4]. Standards developed by SDOs, that is, privately developed technical standards, may be adapted by agencies during the rulemaking process [5]. A standard may not be (and often is not) printed within the final rule; instead, the text of the standard is "incorporated by reference" into the rule. The standard is thus referred to within the final and binding rule as published in the *Code of Federal Regulations*, but the full text of the standard is not reprinted within [5].

This practice raises several issues for law students, scholars, and those in industry: Where is the standard published, if not in the *Code of Federal Regulations*? What is the impact of this practice on those regulated by government agencies? This lack of clarity is not a minor issue; according to the National Institute of Standards (NIST) Standards Incorporated by Reference database (note: unfortunately, not updated since 2016), regulations from the Environmental Protection Agency (EPA) incorporate over 9,000 standards from SDOs, such as 3M Corporation, ASTM International, and the American Society of Mechanical Engineers [6]. The EPA, it should be noted, regulates the agriculture, automotive, construction, electric utilities, oil and gas, and transportation sectors. Where does an interested party find the relevant standard? The answer is not simple.

Suppose that you are a member of the information technology team at a large health care system. Your team uses the Acme Electronic Health Record Platform, and a question has arisen regarding privacy controls in the platform. In order to research this issue, you turn to the U.S. Department of Health and Human Services, which directs you to Title 45 of the *Code of Federal Regulations* (C.F.R.), subtitle A, subchapter D [7]. Subchapter D covers "Health Information Technology." You find the section addressing privacy in 45 C.F.R. 170.205 (o):

> § 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.
>
> The Secretary adopts the following content exchange standards and associated implementation specifications:

U.S. Rulemaking Process

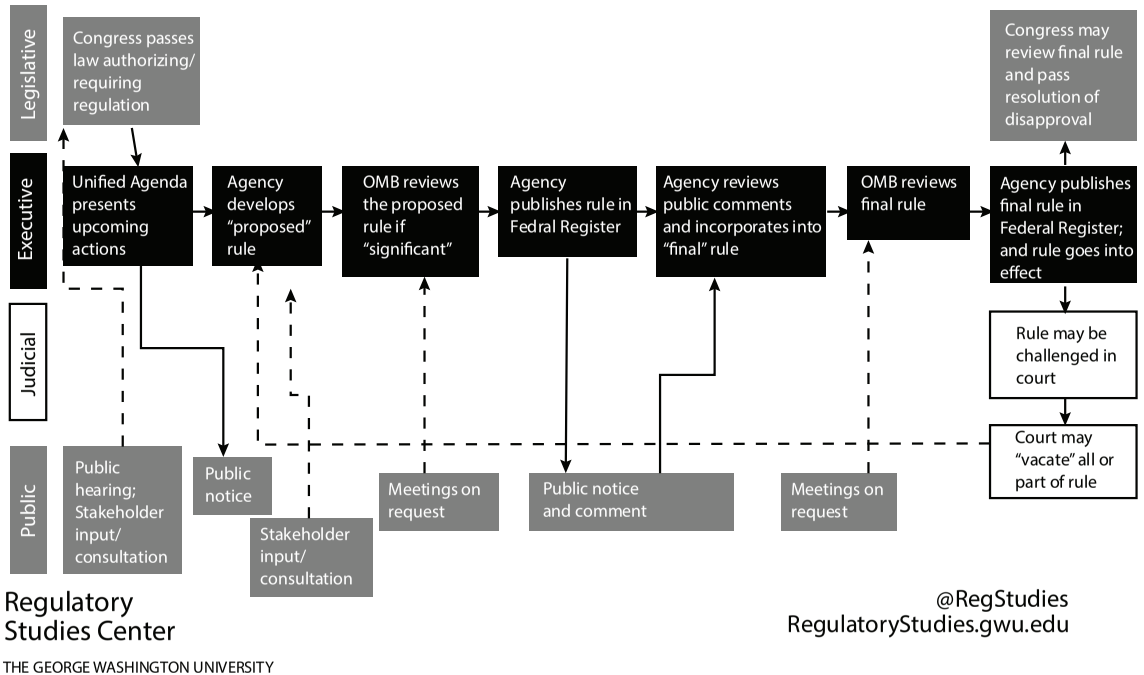

FIG. 12.1. U.S. rulemaking process modified from the George Washington University Regulatory Studies Center.

(o) Data segmentation for privacy—

(1) Standard. HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1 (incorporated by reference in § 170.299).

(2) [Reserved] [8].

Next, as directed, you turn to 45 C.F.R. 170.299, which states:

§ 170.299 Incorporation by reference.

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish a document in the Federal Register and the material must be available to the public. All approved material is available for inspection at the U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, 330 C Street SW., Washington, DC 20201, call ahead to arrange for inspection at 202-690-7151, and is available from the sources listed below. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html [9].

Subsequently listed within the section are no less than 15 SDOs, including the American National Standards Institute (ANSI), ASTM International, and the International Telecommunication Office. You then search for the "HL7 Implementation Guide: Data Segmentation for Privacy" referenced in 45 C.F.R. 170.205 (o) [8]. The guide is referenced in 45 C.F.R. 299 (f) (25) and is available by contacting Health Level Seven International (HL7) with address information provided in 45 C.F.R. 299 (f) [8]. You then, as directed, visit the website given for HL7, a company that provides standards to the health care industry's administrative data sector, and type the name of the standard into the search bar [10]. The search results direct you to the appropriate web page, where you can read a summary of the standard and download a zip file of the document [11]. Finally, the needed information is found. This laborious process, unfortunately, is more common than not.

An excellent resource exploring the issues surrounding this topic may be found in Emily Bremer's teaching guide, "Technical Standards meet Administrative Law: A Teaching Guide on Incorporation by Reference" [5].

INTELLECTUAL PROPERTY AND TECHNOLOGY LAW

Intellectual property is a broad term that encompasses patents, copyrights, trademarks, and trade secrets, or as elegantly described by the World Intellectual Property Organization, encompasses "creations of the mind" [12]. An in-depth discussion of intellectual property law may be viewed at Cornell University's Legal Information Institute website [13], but, for the purposes of this discussion, we will cover the intersection of standards with patent law and with copyright law.

Patents

The roots of patent law in the United States began with a proposal by Representative Thomas Jefferson at the Constitutional Convention of 1789. This proposal led to a provision in section 8, article 8 of the Constitution authorizing Congress "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." The purpose of patent law is to encourage inventors to produce utilitarian works in exchange for exclusive rights for a limited period, with the goal being the enrichment of the public domain [13, 14].

Statutory requirements for patentable inventions are found in Title 35 of the U.S. Code. There are several requirements that inventions must meet for the Patent and Trademark Office (PTO) to issue a patent (for example, the patent application must explain the utility of the claimed invention). The patent permits the owner to exclude others from making, selling, using, offering for sale, or importing the claimed invention, all for a term of approximately 20 years. Patent terms are dependent on several factors; it is best to consult with an attorney for a precise determination [13, 14].

The patent application process is notoriously complex, time-consuming, and costly. Even after a patent is granted, additional issues may arise in relation to the creation of standards. Attorney Melissa Steinman expertly summarizes the issue in a blog post:

> There is a fundamental conflict between broad [intellectual property] rights (the exclusive rights granted to an inventor by patent [. . .]) and the necessity of interoperability in the digital economy. In creating standards, the challenge is to balance (a) the individual ownership rights recognized by patent [. . .] laws; (b) the competition values protected by antitrust laws; and (c) the need for compatibility of competitors' products [15].

To realize financial benefits from the grant of the patent, a patent holder is incentivized to offer access to the patented technology through contractual agreements. If a patent is deemed "essential" to a technology, it is a "standard-essential patent" or "SEP" and may be licensed by SDOs to use in developing standards. The surrounding issues are complex and are explored in the book *Patents and Standards: Practice, Policy, and Enforcement* (please visit the open access fourth chapter, "Standards and Intellectual Property Rights Policies") [16]. An excellent teaching guide on this topic has been created by University of Pennsylvania Professor Cynthia L. Dahl, "When Standards Collide with Intellectual Property: Teaching about Standard Setting Organizations, Technology, and *Microsoft v. Motorola*" [17].

Copyright

Grounded in the U.S. Constitution, copyright law is a form of protection for original works of authorship, including "literary, dramatic, musical, architectural, cartographic, choreographic, pantomimic, pictorial, graphic, sculptural, and audiovisual productions" [18]. For a limited time period, copyright provides the holder with the right to reproduce, to make derivative works, to distribute, to publicly perform, and to display the work. Not all works are protected by the copyright law; some may be aged out of the system or may be protected by a license agreement (e.g., a contract between parties or a Creative Commons license) or belong to a class of items that are not copyrightable (e.g., law or government documents) [19].

Carved out of these rights is the fair use doctrine, which permits selective use of a work in order to, among other things, promote research and scholarship. The fair use doctrine is a checklist of four factors that must be weighed to determine whether a use should be deemed fair. The factors examined are: (1) what is the purpose and the character of the use; (2) what is the nature of the copyrighted work; (3) what is the amount and substantiality of the portion used in relation to

the copyrighted work as a whole; and (4) what is the effect of the use on the potential market for, or value of, the copyrighted work. The fair use doctrine is applied by courts on a case-by-case basis [13].

Copyright issues are implicated throughout the standards setting. As summarized by Bremer:

> Copyright law presents at least three issues. The first is the eligibility of standards for copyright protection. . . . The second is whether and under what circumstances a government reproduction of copyrighted work may constitute a fair use. . . . The third issue is whether a standard loses its copyright protection when a government entity adopts that standard as a law or incorporates it by reference into law [5].

Turning to the "incorporation by reference" doctrine, which also was discussed above in the administrative law section, note that there is an inherent tension between public access to state law and private SDOs' claimed copyrights in standards. This tension can be seen in a recent case out of New York federal court. An SDO sued an online publisher for providing access to the full text of state code, including the standards that had been "incorporated by reference" into the code [20]. Recall here that copyright law does not apply to certain classes of work, such as law, which fall into the public domain. In a lengthy opinion exploring many aspects of copyright law and standards, the court stated: "At bottom, the controlling authorities make clear that a private party cannot exercise its copyrights to restrict the public's access to the law" [20]. The matter on the whole, however, is far from resolved as federal court rulings are not binding on other jurisdictions. See, for example, the decision in *American Society for Testing v. Public.Resource.Org, Inc.* [21]. Bremer's teaching guide addresses this issue as well as the issues referenced above [5].

The teaching guides addressed in the above discussion are excellent and are well-suited to discussions in law school classrooms. For a case study that may be used with undergraduates with an interest in law and policy, please view "Case Study #3: Standards in the Law Case Study," found in Part IV of this book.

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