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# Institutional Competence to Balance Privacy and Competing Values: The Forgotten Third Prong of HIPAA Preemption Analysis

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*This Article provides the first in-depth analysis of the preemption provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its major privacy regulation, the HIPAA Privacy Rule, which is widely believed to set a federal floor of privacy protection that leaves states free to set stricter privacy standards. While this belief is generally correct, it is false when state privacy laws impede enumerated public health activities that Congress deemed to have sufficient social value to warrant intrusions on individual privacy. The Privacy Rule does not itself preempt more stringent state privacy laws, but such laws face statutory preemption if they limit access to health data and biospecimens for use in the enumerated public health activities. The Privacy Rule thus is both a ceiling and a floor of privacy standards that apply in the context of these activities, which include emerging and important types of public health surveillance and investigations that require the use of large, interoperable health data networks.*

*This conclusion flies in the face of well-settled rumors about how HIPAA preemption works. This Article sets out to solve the mystery of how a major provision of HIPAA's preemption framework came to be widely forgotten, and why the Privacy Rule seemingly ignored a clear statutory instruction to preempt state privacy laws as necessary to protect certain important public health activities. What emerges is a fascinating tale of*

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*Congress and a regulatory agency grappling with complex preemption choices that implicated not just federalism and individual rights but also important public interests that compete with privacy. Congress struck a balance between privacy and competing public interests in HIPAA's statutory preemption provisions. The Privacy Rule's failure to implement that balance is best explained as an administrative judgment that courts and legislatures, rather than regulatory bodies, possess superior institutional competence to implement the balance Congress struck. The Privacy Rule is a masterpiece of administrative modesty that carefully preserves Congress's preemption choices by ceding implementation responsibilities to other institutions of government.*

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## INTRODUCTION

This Article takes a fresh look at preemption of state privacy laws under the Health Insurance Portability and Accountability Act of 1996 (HIPAA)<sup>1</sup> and one of its major implementing regulations, the HIPAA Privacy Rule.<sup>2</sup> HIPAA's statutory preemption provisions have been a virtual dead zone both in case law and in scholarly literature. Part I explores why this situation is ripe for change. HIPAA preemption is poised to play a crucial role in ordering access to health data and biospecimens for emerging types of public health surveillance and investigations that have the potential to save or improve many people's lives. The activities in question examine insurance claims and other health-related data for very large groups of patients — tens or even hundreds of millions of people — with various goals such as speeding the detection of drug safety risks, unmasking ineffective or wasteful treatments, and understanding disparities in health outcomes among various population subgroups.<sup>3</sup> Recent federal legislation authorizes public health surveillance and investigations that require large-scale, multistate data resources,<sup>4</sup> setting the stage for HIPAA's preemption provisions to be put to the test.

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<sup>1</sup> Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 18, 26, 29, and 42 U.S.C.).

<sup>2</sup> 45 C.F.R. pts. 160, 164 (2007).

<sup>3</sup> See, e.g., PANEL ON PERFORMANCE MEASURES & DATA FOR PUBLIC HEALTH PERFORMANCE PARTNERSHIP GRANTS, NAT'L RESEARCH COUNCIL, HEALTH PERFORMANCE MEASUREMENT IN THE PUBLIC SECTOR 83-94 (Edward B. Perrin et al. eds., 1999), available at <http://www.nap.edu/openbook.php?isbn=0309064368> (discussing the use of administrative databases, such as large claims databases held by health insurers, in public health studies); Fred D. Brenneman et al., *Outcomes Research in Surgery*, 23 WORLD J. SURGERY 1220, 1220-22 (1999) (discussing study methodologies that use large clinical and administrative datasets to assess the effectiveness of various surgical procedures); Barbara J. Evans, *Seven Pillars of a New Evidentiary Paradigm: The Food, Drug, and Cosmetic Act Enters the Genomic Era*, 85 NOTRE DAME L. REV. 419, 455-58 (2010) (discussing large-scale observational studies as a tool for assessing drug safety) [hereinafter *Seven Pillars*]; Jed Weissberg, *Use of Large System Databases*, in THE LEARNING HEALTHCARE SYSTEM: WORKSHOP SUMMARY INSTITUTE OF MEDICINE (IOM), 46, 46 (LeighAnne Olsen et al. eds., 2007) [hereinafter IOM, LEARNING HEALTHCARE], available at [http://books.nap.edu/openbook.php?record\\_id=11903](http://books.nap.edu/openbook.php?record_id=11903) (describing observational research in a large HMO clinical database).

<sup>4</sup> See, e.g., Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of 42 U.S.C. and I.R.C.); *id.* § 6301(a)-(d) (adding provisions to implement a program of comparative clinical effectiveness research, codified at 42 U.S.C. §§ 1320e to 1320e-2 and § 299b-37); Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 905, 121 Stat. 823, 944-49 (codified as amended in scattered sections of 21 U.S.C.); *id.*

Apart from its practical importance, HIPAA preemption presents theoretical problems that this Article introduces with the aim of opening a wider scholarly dialogue about them. The central conundrum of HIPAA preemption, as described in this Article, is that the Privacy Rule ignored a clear statutory instruction to preempt state privacy law in a specific circumstance where Congress determined that individual privacy interests should give way to competing public interests. The agency's regulation is less preemptive than Congress authorized (and indeed instructed) it to be.<sup>5</sup> Ordinarily, an agency's reluctance to preempt state law is unproblematic and deserves great deference,<sup>6</sup> but large and intriguing questions surround the deference (if any) to which the agency is entitled in this instance.

In the context of socio-economic regulation — a context that includes the regulation of medical privacy and data access — administrative preemption decisions are known to implicate federalism and individual rights.<sup>7</sup> An agency's decision not to preempt state law seems trustworthy inasmuch as it is a decision against the agency's interest and shrinks the agency's power in favor of the states. In HIPAA, however, Congress was grappling with a complex set of concerns among which federalism was just one element. Choices about HIPAA preemption implicate individual rights (privacy and dignitary interests in controlling access to one's own health data) and federalism (whether states rather than federal agencies should decide the level of privacy protection). These choices also implicate the balance between individual rights and competing public goods (such

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§ 905 (adding 21 U.S.C. § 355(k)(3) to authorize drug safety surveillance and investigations in a dataset for one hundred million persons).

<sup>5</sup> See discussion *infra* Part II.

<sup>6</sup> See, e.g., William Funk, *Preemption by Federal Agency Action*, in *PREEMPTION CHOICE: THE THEORY, LAW, AND REALITY OF FEDERALISM'S CORE QUESTION* 214, 223-24 (William W. Buzbee ed., 2011) (commenting that “there is asymmetry between judicial consideration of an agency's interpretation that a statute or regulation does preempt state law and an agency's interpretation that a statute or regulation does preempt state law”); see generally Howard P. Walthall, Jr., *Chevron v. Federalism: A Reassessment of Deference to Administrative Preemption*, 28 *CUMB. L. REV.* 715 (1997-1998) (discussing courts' asymmetrical deference to administrative decisions to preempt or not to preempt state law and arguing that the Supreme Court should explicitly adopt an asymmetrical deference approach).

<sup>7</sup> See, e.g., William N. Eskridge, Jr. & Lauren E. Baer, *The Continuum of Deference: Supreme Court Treatment of Agency Statutory Interpretations from Chevron to Hamdan*, 96 *GEO. L.J.* 1083, 1144-45 (2008) (taking *Gonzales v. Oregon*, 546 U.S. 243 (2006), as an exemplar of socio-economic regulation cases and identifying the key issues as determining the extent of the statutory delegation, application of the relevant statute in the factual context of the case, and “contemplating the federalism and individual rights implications of preemption”).

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as biomedical discovery and public health advances that depend on access to individuals' data) and thus present second-order questions of federalism and institutional competence (whether Congress, the agency, the courts, or the states can best strike the balance between privacy and the competing public interests).

On the important matter of public health access to data, Congress trusted no institution other than itself to strike this balance and, having done so, inserted language in HIPAA's statutory preemption provisions to protect data access.<sup>8</sup> The HIPAA Privacy Rule does not give full effect to that language. Here, a modest view of preemption may promote federalism while undermining other important public interests that Congress expressly sought to protect.

Part II challenges the widely held belief that the Privacy Rule merely sets a floor of privacy protection that leaves states free to set stricter privacy standards.<sup>9</sup> While this belief is generally correct, it is false with respect to a very specific — but very important — class of public health activities that Congress deemed to have high social value. These activities include “reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention”<sup>10</sup> conducted pursuant to “any law”<sup>11</sup> (state or federal) [hereinafter, “the enumerated public health activities”]. For the enumerated public health activities, the Privacy Rule does not itself preempt more stringent state privacy laws. However, HIPAA's *statutory* preemption provisions have the effect of making the HIPAA Privacy Rule both a ceiling and a floor.<sup>12</sup> Thus, the HIPAA statute preempts state privacy laws — even ones that are more stringent than the HIPAA Privacy Rule — in situations where the state laws would interfere with public health surveillance and investigations.<sup>13</sup>

These conclusions stand in stark contrast to well-settled beliefs about how HIPAA preemption works, yet they have unambiguous textual support in the HIPAA statute. Part II focuses first on the textual arguments. Then, it advances other arguments, not as an aid to interpreting the HIPAA statute (which speaks for itself) but because they help shed light on why the statute and regulation are configured as they are. HIPAA's muscular protection of public health laws appears very deliberate. Statements in the legislative record support the view

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<sup>8</sup> See discussion *infra* Part II.

<sup>9</sup> See *infra* notes 65-68 and accompanying text.

<sup>10</sup> 42 U.S.C. § 1320d-7(b) (2010).

<sup>11</sup> *Id.*

<sup>12</sup> See discussion *infra* Part II.

<sup>13</sup> *Id.*

that Congress fully intended to write the strong preemption provisions that the HIPAA statute contains. HIPAA's statutory preemption provisions, which employ a three-pronged preemption analysis, are not unique in doing so and in fact follow an approach seen in other important federal legislation in the health law field.

Part III explores how the statute and Privacy Rule relate to each other. The weaker preemption provisions of the HIPAA Privacy Rule do not displace or alter the stronger preemption provisions of the HIPAA statute. Both preemption provisions stand together in a relationship that this Article clarifies. While not setting a broad, general ceiling for state privacy standards, the HIPAA statute creates what might be called a "canopy" to shelter specific, socially important data uses from more stringent state privacy laws. When enacting HIPAA in 1996, Congress thus embraced a mechanism — narrow, conduct-specific ceilings — that Professor Schwartz recently proposed as a possible approach to try in the privacy law area.<sup>14</sup> In HIPAA's case, Congress already has tried this approach but, unfortunately, its advantages are not yet manifest because, apparently, the critical provision — which adds a third prong to HIPAA preemption analysis — is a forgotten statute. This Article seeks to call it back from the dead.

#### I. PRIVACY, PREEMPTION, AND PUBLIC HEALTH

The HIPAA statute was enacted on August 21, 1996 and recently marked its sixteenth anniversary. In those sixteen years, no court has ever decided a case that posed a HIPAA preemption question in the context of public health surveillance and investigations. In their fascinating survey of 113 HIPAA preemption cases litigated through the fall of 2006,<sup>15</sup> Sara Rosenbaum et al. did not find any case in which the underlying controversy involved access to data or tissue resources

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<sup>14</sup> Paul M. Schwartz, *Preemption and Privacy*, 118 YALE L.J. 902, 943 (2009) (noting that "[e]ven when there is a strong argument for uniformity of regulatory action, and, hence, a federal ceiling, there are merits to narrowing the ceiling to specific conduct rather than the entire subject matter"); see also *id.* at 946 (noting that: "[i]t is also important to work with concepts beyond the classic preemptive categories of 'floors' and 'ceilings.' One such concept concerns the possibility of limiting ceiling preemption only to certain specific conduct rather than an entire subject matter. In 2003, FACTA [Fair and Accurate Credit Transactions Act 15 U.S.C. §§ 1681-1681x] demonstrated the feasibility of such an approach to the jurisprudence of preemption.").

<sup>15</sup> Sara Rosenbaum, Phyllis Borzi, Taylor Burke & Sonia W. Nath, *Does HIPAA Preemption Pose a Legal Barrier to Health Information Transparency and Interoperability?*, 15 BNA HEALTH CARE POL'Y REP. 1, 1-13 (2007).

to use in such activities.<sup>16</sup> A more recent search of all state and federal cases decided between 1996 and July 2012 found only two HIPAA-related cases that ever cited 42 U.S.C. § 1320d-7(b),<sup>17</sup> the provision that defines the enumerated public health activities and affords them special protection.<sup>18</sup> The two cases that cited § 1320d-7(b) had nothing to do with public health surveillance or investigations.<sup>19</sup>

Those whom this provision aims to help — members of the medical and public health communities seeking access to data and tissue resources to improve the public's health — perhaps have a negative perception of lawyers and are reluctant to turn to courts to clarify confusion about the law. As a consequence, rumor rather than valid statutory interpretation has informed much of the debate about HIPAA preemption and public health access to data. Discussions of HIPAA preemption often rely heavily on secondary sources of literature and, less frequently, on regulations, but almost never consult the relevant statutes. For example, the Institute of Medicine, a highly respected advisory body that typically produces rigorous, peer-reviewed analyses of policy issues affecting biomedical research, discussed HIPAA preemption in a recent report without once citing the preemption provisions of the HIPAA statute.<sup>20</sup> Beliefs about HIPAA preemption are

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<sup>16</sup> See *id.* at 6, fig.2 (showing the following contexts in which the 113 HIPAA preemption challenges have been brought: wrongful death (3 cases); public information requests (5); product liability (5); probate (3); other negligence (12); medical malpractice (29); Medicaid reimbursement (1); insurance (8); intentional tort (1); fraud (9); DUI (8); divorce (1); discrimination (6); criminal indictment (1); constitutional (12); child pornography (1); child custody (7); and bankruptcy (1)).

<sup>17</sup> A search conducted in Westlaw's All State and Federal case database on July 25, 2012, using the search phrase "Health Insurance Portability and Accountability Act" & "1320d-7(b)" located two cases: *Seaton v. Mayberg*, 610 F.3d 530, 541 (9th Cir. 2010) (finding that use of a convicted, sexually violent predator's medical records in the context of a civil commitment proceeding was a public health use allowed under 42 U.S.C. § 1320d-7(b)); and *White v. Arkansas*, 259 S.W.3d 410, 415 (Ark. 2007) (discussing the admissibility of a defendant's HIV test results in a criminal proceeding and incorrectly citing 42 U.S.C. § 1320d-7(b) as providing that "nothing within the Act is to be construed to limit a state's authority to investigate crimes," which this provision does not do).

<sup>18</sup> See discussion *infra* Part II.

<sup>19</sup> See *supra* note 17 and accompanying text.

<sup>20</sup> See COMM. ON HEALTH RESEARCH AND THE PRIVACY OF HEALTH INFO., INST. OF MED., *BEYOND THE HIPAA PRIVACY RULE: ENHANCING PRIVACY, IMPROVING HEALTH THROUGH RESEARCH* 66 (Sharyl Nass, Laura A. Levit, & Lawrence O. Gostin eds., 2009), available at <http://www.nap.edu/catalog/12458.html> [hereinafter IOM, *PRIVACY REPORT*] (never citing in any of its footnotes, endnotes, or text the statutory preemption provisions of HIPAA located at section 1178 of the Social Security Act, codified at 42 U.S.C. § 1320d-7).

circulated and recirculated in the secondary literature and eventually attain the status of well-settled rumor.

Even among law scholars, the HIPAA preemption provisions have attracted little interest. As a crude but indicative measure, contrast the volume of HIPAA preemption scholarship with the volume of scholarship on preemption under the Employee Retirement Income Security Act of 1974 (ERISA).<sup>21</sup> Searching for the phrase “ERISA preemption clause” in Westlaw’s Journals and Law Reviews (JLR) database locates 661 documents.<sup>22</sup> In contrast, a JLR search on the phrase “HIPAA preemption clause” locates only five documents. Searches for the phrases “ERISA preemption provision” and “HIPAA preemption provision” locate 849 and 13 documents, respectively. Adjusting for the difference in the two statutes’ ages, “ERISA preemption clause” already had garnered 66 mentions in the scholarly literature (and “ERISA preemption provision” had received 82) by 1990 when ERISA was 16 years old, the same age HIPAA is now. No testable hypothesis can resolve why there has been so little HIPAA preemption scholarship. An untestable but plausible hypothesis may be that few have written about HIPAA’s preemption provisions because few ever read them.

An alternative and more encouraging lesson from these statistics is that 90% of ERISA preemption scholarship was penned after the statute’s sixteenth anniversary in 1990. HIPAA preemption may simply be a “late bloomer” too. Interest in ERISA preemption flowered in the 1990s in response a specific triggering event: the rise of managed care.<sup>23</sup> As managed care health plans implemented cost-saving policies, states responded with patients’ rights legislation and recognized new causes of action for patients whose health plans had refused to pay for needed care.<sup>24</sup> These state reforms incited a debate about preemption under the federal ERISA statute, which regulates employer-sponsored health plans.<sup>25</sup> ERISA — a narrowly technical

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<sup>21</sup> Employee Retirement Income Security Act (ERISA) of 1974, Pub. L. 93-406, 88 Stat. 829 (codified as amended at 29 U.S.C. § 1001 *et seq.*).

<sup>22</sup> Online search for ERISA preemption clause, Westlaw.com (July 30, 2012).

<sup>23</sup> See *Pegram v. Herdrich*, 530 U.S. 211, 218-19 (2000) (discussing the emergence of Health Maintenance Organizations (HMOs), a form of managed care, and how they differ from traditional “fee-for-service” health insurance plans).

<sup>24</sup> See BARRY R. FURROW ET AL., *THE LAW OF HEALTH CARE ORGANIZATION AND FINANCE* 242-43 (5th ed. 2004) (noting that, in response to perceived abuses by managed care health plans, “[a]lmost every state adopted some form of legislation, nearly 1000 statutes in all, during the last half of the 1990s”).

<sup>25</sup> See *DiFelice v. Aetna U.S. Healthcare*, 346 F.3d 442, 454 & n.1 (3d Cir. 2003) (Becker, J., concurring) (commenting on the “Serbonian bog” of ERISA preemption



statute intended to regulate employee pension and benefit programs — emerged as “[t]he most important federal statute affecting health insurance,”<sup>26</sup> a traditional area of state responsibility.<sup>27</sup> ERISA had a profound deregulatory impact “insofar as it has been interpreted to preempt a broad range of state laws.”<sup>28</sup>

HIPAA preemption has not yet bared its deregulatory fangs, perhaps for lack of a context in which it needed to do so. That context is unfolding now. Envisioning the future of public health law requires — first of all — an appreciation of profound changes that already have occurred in the field of public health. During the first decade of this century, post-1980s advances in the life sciences and information technology bore bountiful fruit.<sup>29</sup> This harvest included improved methodologies for informational research<sup>30</sup> — that is, epidemiological and laboratory studies that use data and biospecimens<sup>31</sup> as opposed to

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issues that arose in the context of managed care cases and defining a Serbian bog as “a mess from which there is no way of extricating oneself”).

<sup>26</sup> See FURROW ET AL., *supra* note 24, at 272 (commenting prior to passage of the Patient Protection and Affordable Care Act, which seems destined to have an even greater impact).

<sup>27</sup> *Id.*

<sup>28</sup> *Id.* at 272-73.

<sup>29</sup> See, e.g., Francis S. Collins, Eric D. Green, Alan E. Guttmacher & Mark S. Guyer, *A Vision for the Future of Genomics Research*, 422 NATURE 835, 835-47 (2003) (discussing impacts of the Human Genome Project); see also Brenneman et al., *supra* note 3 (discussing the growing importance of data-oriented outcomes research after 1980); Agency for Healthcare Research and Quality, *Outcomes Research Fact Sheet (2000)*, AHRQ.GOV, <http://www.ahrq.gov/clinic/outfact.htm> (last visited Oct. 12, 2011) [hereinafter AHRQ, Fact Sheet] (same).

<sup>30</sup> “Informational research” is one of many terms that refer to studies that use data and biospecimens. See, e.g., Protection of Human Subjects of Biomedical and Behavioral Research, 43 Fed. Reg. 56,174, 56,181,182 (Nov. 30, 1978) [hereinafter HEW, 1978 REPORT] (using the term “research using . . . records” to refer to research that studies preexisting data); BENGT D. FURBERG & CURT D. FURBERG, *EVALUATING CLINICAL RESEARCH: ALL THAT GLITTERS IS NOT GOLD* 29-37 (2d ed. 2007) (using the term “observational” to refer to methodologies that study data); IOM, *PRIVACY REPORT*, *supra* note 20, at 7 (distinguishing “information-based” research from clinical research); David Casarett, Jason Karlawish, Elizabeth Andrews & Arthur Caplan, *Bioethical Issues in Pharmacoepidemiologic Research*, in PHARMACOEPIDEMOLOGY 587, 588 (Brian L. Strom ed., 4th ed. 2005) (using the term “epidemiologic research”); Brian L. Strom, *Study Designs Available for Pharmacoepidemiology Studies*, in PHARMACOEPIDEMOLOGY, *supra* at 21-26 (discussing the array of scientific methodologies — including observational studies that use existing data — for studying how people react to drugs).

<sup>31</sup> See Brenneman et al., *supra* note 3, 1220-22 (discussing growth of informational research); AHRQ, Fact Sheet, *supra* note 29 (same); see also Barbara J. Evans & Eric M. Meslin, *Encouraging Translational Research Through Harmonization of FDA and Common Rule Informed Consent Requirements for Research with Banked Specimens*, 27 J.

interventional (clinical) approaches<sup>32</sup> that use whole-body human research subjects. Informational methodologies are now sufficiently well-developed and informative to play a more prominent role in biomedical evidence generation. This marks an epochal shift in the relative mix of informational and clinical studies that will be performed going forward.<sup>33</sup> Data and biospecimens have become crucial resources for advancing science, improving the public's health, and — it is hoped — identifying ways to make today's wasteful healthcare sector less ruinous to our nation's fiscal prognosis.<sup>34</sup>

In this new environment, privacy and ethical protections that unduly restrict access to data and biospecimens can very literally kill people. A disquieting example is that it took sixty-five months for the U.S. Food & Drug Administration (FDA) to confirm that rofecoxib (Vioxx) was causing cardiovascular problems and needed to be removed from the market.<sup>35</sup> Dr. Platt subsequently demonstrated that the safety problem could have been detected in about half that time — thirty-four months — if the FDA had been able to conduct safety surveillance using insurance claims data for seven million persons.<sup>36</sup>

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LEGAL MED. 119, 122 (2006) (discussing the growing importance of research with biospecimens); Rina Hakimian & David Korn, *Ownership and Use of Tissue Specimens for Research*, 292 JAMA 2500, 2500 (2004) (same).

<sup>32</sup> See LAWRENCE M. FRIEDMAN, CURT D. FURBERG & DAVID L. DEMETS, *FUNDAMENTALS OF CLINICAL TRIALS* 2-5 (3d ed. 1998) (discussing clinical research, exemplified by a randomized, controlled clinical trial that monitors outcomes prospectively in two groups of people who either are or are not subjected to a particular treatment).

<sup>33</sup> See IOM, *LEARNING HEALTHCARE*, *supra* note 3, at 128, 130 (discussing the growing use of observational methodologies); Evans, *Seven Pillars*, *supra* note 3, at 479-85 (same); see also 21 U.S.C.A. § 355(o)(3)(D) (West 2010 & Supp. 2011) (providing an example of recent legislation that requires the U.S. Food and Drug Administration to consider and reject the use of observational studies before it can order a clinical drug trial during the postmarketing period after drugs are approved).

<sup>34</sup> See, e.g., *ROUNDTABLE ON VALUE & SCIENCE-DRIVEN HEALTHCARE*, INST. OF MED., *CLINICAL DATA AS THE BASIC STAPLE OF HEALTH LEARNING: CREATING AND PROTECTING A PUBLIC GOOD: WORKSHOP SUMMARY 1* (Claudia Grossmann, Alex W. Goodby, LeighAnne Olsen & Michael McGinnis rapporteurs, 2010) (stating that “clinical data represent the resource most central to healthcare progress” and listing various potential uses to develop new knowledge, identify best healthcare practices, and eliminate waste and inefficiencies to control healthcare spending); see also Diana Manos, *GAO: Healthcare Costs Threaten to Undo American Economy*, HEALTHCARE FIN. NEWS (Jan. 31, 2008), <http://www.healthcarefinancenews.com/news/gao-healthcarecosts-threaten-to-undo-american-economy>.

<sup>35</sup> Evans, *Seven Pillars*, *supra* note 3, at 456.

<sup>36</sup> Richard Platt, *Considerations for Creating an Active Surveillance System*, in *CHALLENGES FOR THE FDA: THE FUTURE OF DRUG SAFETY*, WORKSHOP SUMMARY 35, 36-43 (Leslie Pray & Sally Robinson rapporteurs, 2007); Richard Platt, Remarks at the Food

Surveillance in a one-hundred-million-person dataset could have confirmed the problem in three months (plus, of course, the several months it generally requires for insurance claims data to “settle down” after a patient receives healthcare).<sup>37</sup>

Confidentiality — the simple and widely held notion that information shared in the medical treatment relationship should not be disclosed to third parties except as the patient has authorized<sup>38</sup> — is a highly valued good. It competes with other desirable goods that could flow from wider use of data and biospecimens in informational studies. In the example just given, these goods include lives that might have been saved and a boost to quality-adjusted life years in people who could have escaped a debilitating stroke, if only it had been possible to conduct public health surveillance in a one hundred-million-person dataset.

Congress and state legislatures throughout our nation’s history have possessed the power to order actions to promote the public’s health.<sup>39</sup> In the modern context, this includes the power to authorize programs that require the use of people’s health data and biospecimens. Shortly after Platt’s data were reported to the FDA and Institute of Medicine,<sup>40</sup> Congress took such action in the Food and Drug Administration Amendments Act of 2007,<sup>41</sup> which authorizes pharmacoepidemiological<sup>42</sup> studies of postmarket drug safety using data for one hundred million Americans.<sup>43</sup> Congress also called for large-scale informational studies in the comparative effectiveness provisions of the Patient Protection and Affordable Care Act of

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and Drug Administration, Sentinel Network Public Meeting 67-70 (Mar. 7, 2007), available at <http://www.fda.gov/downloads/Safety/FDAsSentinelInitiative/ucm116513.pdf> [hereinafter *FDA*].

<sup>37</sup> Platt, *FDA*, *supra* note 36, at 70.

<sup>38</sup> See, e.g., THE AMERICAN HERITAGE MEDICAL DICTIONARY (2007), available at <http://medical-dictionary.thefreedictionary.com/confidentiality> (defining confidentiality as “[t]he ethical principle or legal right that a physician or other health professional will hold secret all information relating to a patient, unless the patient gives consent permitting disclosure”).

<sup>39</sup> See Barbara J. Evans, *Much Ado About Data Ownership*, 25 HARV. J.L. & TECH. 69, 79, 114-19 (2011) [hereinafter *Much Ado*].

<sup>40</sup> See sources cited *supra* note 36.

<sup>41</sup> Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (codified as amended in scattered sections of 21 U.S.C.).

<sup>42</sup> See Brian L. Strom, *What is Pharmacoepidemiology?*, in PHARMACOEPIDEMIOLOGY, *supra* note 30, at 11 (defining pharmacoepidemiology as “the study of the use of and the effects of drugs in large numbers of people”).

<sup>43</sup> 21 U.S.C.A. § 355(k)(3)(B)(ii) (West 2010 & Supp. 2011); *id.* § 355(k)(3)(C).

2010.<sup>44</sup> Public health legislation (both state and federal) authorizing studies of people's health data and biospecimens is likely to be a recurring feature of the twenty-first century legal landscape.

There is great concern that privacy laws may thwart the objectives of these types of public health statutes. The HIPAA statute focused primarily on insurance and healthcare fraud issues, but it also expanded federal regulation of medical privacy and data security. The Administrative Simplification provisions in Subtitle F of Title II of HIPAA<sup>45</sup> required the Secretary of the U.S. Department of Health & Human Services (HHS) to develop a group of interrelated regulations.<sup>46</sup> Authority to develop Standards for the Privacy of Individually Identifiable Health Information (the "Privacy Rule"<sup>47</sup>) appears in section 264 of HIPAA, which is codified as a note to 42 U.S.C. § 1320d-2. The main text of § 1320d-2 authorizes HHS to develop various other regulations such as the Transactions Rule<sup>48</sup> published in August 2000, the Security Rule<sup>49</sup> promulgated in 2003, and standards for unique patient identifying numbers which proved controversial and encountered delays.<sup>50</sup>

HIPAA deposited a new layer of federal regulations onto a field already densely covered with state law.<sup>51</sup> When healthcare providers

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<sup>44</sup> Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of 42 U.S.C. and I.R.C.); *id.* § 6301(a)-(d); 42 U.S.C. §§ 1320e to 1320e-2 and § 299b-37 (providing for a program of clinical comparative effectiveness research).

<sup>45</sup> Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, §§ 261-264, 110 Stat. 1936, 2021-34 (codified primarily in 42 U.S.C. §§ 1320d-1320d-8 as "Part C — Administrative Simplification").

<sup>46</sup> *Id.*; see also Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,463 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160, 164) (discussing, in the preamble to the HIPAA Privacy Rule, the "set of interlocking regulations" promulgated pursuant to HIPAA's Administrative Simplification provisions).

<sup>47</sup> Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,462.

<sup>48</sup> Health Insurance Reform: Standards for Electronic Transactions, 65 Fed. Reg. 50,312, 50,312,313 (Aug. 17, 2000) (to be codified at 45 C.F.R. pts. 160, 162).

<sup>49</sup> Health Insurance Reform: Security Standards, 68 Fed. Reg. 8334, 8334 (Feb. 20, 2003) (to be codified at 45 C.F.R. pts. 160, 162, 164).

<sup>50</sup> See IOM, PRIVACY REPORT, *supra* note 20, at 154 (noting that Congress delayed implementation of a standard for the unique patient identifier by the Centers for Medicare & Medicaid Services by inserting language into annual appropriations bills).

<sup>51</sup> See *Implementation of the Federal Standards for Privacy of Individually Identifiable Health Information; Hearings Before the Subcomm. on Privacy and Confidentiality of the National Comm. on Vital and Health Statistics*, § II (Oct. 30, 2002) (testimony of Joy L. Pritts), available at <http://www.ncvhs.hhs.gov/021030p6.htm> (discussing states' efforts

and insurers initially began to comply with the HIPAA Privacy Rule in 2003-2004,<sup>52</sup> there already was a “patch quilt”<sup>53</sup> of state privacy statutes<sup>54</sup> as well as a large body of common law, such as evidentiary privileges that protect medical communications and tort causes of action for privacy violations.<sup>55</sup> In an excellent recent study, John W. Hill et al. explain how daunting this state-by-state patchwork has become.<sup>56</sup> They argue that it threatens to obstruct the development of large, interoperable health data systems.<sup>57</sup> Interoperable data networks that muster data for tens or hundreds of millions of persons are, of course, a critical infrastructure for the types of large-scale public health surveillance and investigations<sup>58</sup> described in recent legislation.<sup>59</sup> Not all public health studies require nationally-scaled data infrastructures, but a number of very promising approaches do.<sup>60</sup>

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over many years to refine medical privacy standards and adapt them for changes in the healthcare industry) [hereinafter Pritts’ Testimony].

<sup>52</sup> See 45 C.F.R. § 164.534 (2013) (establishing the Privacy Rule’s effective compliance dates).

<sup>53</sup> Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 59,918, 60,010 (proposed Nov. 3, 1999) (to be codified at 45 C.F.R. pts. 160-164) (noting that: “states themselves have a patch quilt of laws that fail to provide a consistent or comprehensive policy, and there is considerable variation among the states in the scope of the protections provided. Moreover, health data is becoming increasingly ‘national’; as more information becomes available in electronic form, it can have value far beyond the immediate community where the patient resides. Neither private action nor state laws provide a sufficiently rigorous legal structure to correct the market failure now or in the future. Hence, a national policy with consistent rules is a vital step toward correcting the market failure that exists.”).

<sup>54</sup> See generally JOY PRITTS, ANGELA CHOY, LEIGH EMMART & JOANNE HUSTEAD, *THE STATE OF HEALTH PRIVACY: A SURVEY OF STATE HEALTH PRIVACY STATUTES* (2d ed. 2003), available at <http://hpi.georgetown.edu/privacy/pdfs/statereport1.pdf> (Vol. 1) and <http://hpi.georgetown.edu/privacy/pdfs/statereport2.pdf> (Vol. 2) (summarizing in two volumes state privacy-related statutes in place as of 2003).

<sup>55</sup> See generally Qual-Rx, Inc., *Evaluation of State Privacy Law in Relation to the Sentinel Initiative* (July 12, 2010), available at <http://www.regulations.gov/documentDetail;D=FDA-2009-N-0192-0015> (attempting to summarize, in a report prepared in connection with the Food & Drug Administration’s Sentinel drug-safety surveillance activities, the diversity of state privacy laws including tort causes of action).

<sup>56</sup> John W. Hill, Arlen W. Langvardt, Anne P. Massey & Jonathan E. Rinehart, *A Proposed National Health Information Network Architecture and Complementary Federal Preemption of State Health Information Privacy Laws*, 48 AM. BUS. L.J. 503, 514 (2011).

<sup>57</sup> *Id.* at 514, 521-34.

<sup>58</sup> See, e.g., Evans, *Much Ado*, *supra* note 39, at 86-106 (discussing the data and infrastructure resources necessary to support promising lines of public health studies and biomedical research).

<sup>59</sup> See *supra* notes 41, 44.

<sup>60</sup> Evans, *Much Ado*, *supra* note 39, at 92.

Thus, maintaining state-by-state privacy requirements has the potential to stall important public health initiatives by impeding access to data and biospecimens.

The HIPAA Privacy Rule's effect on state law is addressed in two places: in the HIPAA statute<sup>61</sup> and in the HIPAA Privacy Rule.<sup>62</sup> On January 25, 2013, HHS published a final rule introducing various changes to the HIPAA Privacy Rule.<sup>63</sup> These changes, effective on March 26, 2013, did not alter the Privacy Rule's preemption provisions that are the focus of this Article.<sup>64</sup> There is a widely held belief — indeed, it appears to be almost universally believed — that the HIPAA Privacy Rule provides a federal floor on privacy protections but leaves states free to set higher privacy standards: “While the Privacy Rule generally preempts contrary state law, it permits contrary state laws that are ‘more stringent’ than the Privacy Rule to remain in place.”<sup>65</sup> HHS, which implements HIPAA, has interpreted “more stringent” in a way that would let states restrict the use and disclosure of data and tissue (biospecimen) resources to a greater degree than HIPAA's privacy protections do.<sup>66</sup> Thus, it is believed, “the [HIPAA] Privacy Rule constitutes a federal floor of protection rather than a ceiling, guaranteeing a minimum level of federal protection while allowing more privacy-protective state law provisions to survive preemption.”<sup>67</sup>

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<sup>61</sup> 42 U.S.C. § 1320d-7 (2006).

<sup>62</sup> 45 C.F.R. §§ 160.201-160.205 (2013).

<sup>63</sup> Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, 78 Fed. Reg. 5566 (final rule Jan. 25, 2013).

<sup>64</sup> See *id.* at 5566 (stating an effective date of Mar. 26, 2013); *id.* at 5689-90 (not introducing revisions to the preemption provision at 45 C.F.R. § 160.203, which is the subject of this Article).

<sup>65</sup> Pritts' Testimony, *supra* note 51, Introductory Remarks; see also Martha Tucker Ayres, *Confidentiality and Disclosure of Health Information in Arkansas*, 64 ARK. L. REV. 969, 1015 (2011) (stating that “HIPAA preempts any state law which is contrary to it, unless state law is more stringent in its individual privacy protections”); U.S. Dep't of Health & Human Servs., *Does the HIPAA Privacy Rule preempt State laws?*, HHS.GOV, <http://www.hhs.gov/hipaafaq/state/399.html> (last updated Dec. 11, 2006) (stating that “[t]he HIPAA Privacy Rule provides a Federal floor of privacy protections for individuals' individually identifiable health information where that information is held by a [HIPAA-]covered entity or by a business associate of the covered entity”).

<sup>66</sup> 45 C.F.R. § 160.202 (2013); see also Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 78 Fed. Reg. 5566, 5690 (final rule, Jan. 25, 2013) (introducing a technical amendment to reflect the fact that the HIPAA Privacy Rule now applies to business associates as well as covered entities, but not altering the regulation's basic definition of “more stringent”).

<sup>67</sup> Grace Ko, *Partial Preemption Under the Health Insurance Portability and*

“In effect, the privacy rule creates a minimum level of privacy protection rather than a maximum.”<sup>68</sup>

Based on this belief, some members of the research and public health communities call for broader HIPAA preemption of state privacy laws that hinder access to data and biospecimens.<sup>69</sup> In their study, John W. Hill et al. argue that congressional action to impose uniform federal privacy standards would survive constitutional challenges.<sup>70</sup> Writing before the recent decision in *NFIB v. Sebelius*, they relied heavily on Commerce Clause arguments that may have lost a bit of their punch after that decision.<sup>71</sup> Still, it remains a fact that the HIPAA statute and Privacy Rule have a long track record of surviving constitutional challenges.<sup>72</sup> Moreover, Congress has a long tradition of regulating interstate public utilities and seemingly has ample power to address barriers to the development of interstate health data networks, if Congress so desires.<sup>73</sup>

The problem, however, is that Congress appears to lack this desire. An excellent opportunity to address this problem came and went when Congress introduced major amendments to the HIPAA statute in the 2009 Health Information Technology for Economic and Clinical

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*Accountability Act*, 79 S. CAL. L. REV. 497, 505 (2006); see also Hill et al., *supra* note 56 at 516 (stating that “[t]he Privacy Rule supersedes only those state laws that directly contradict it or that provide less protection”).

<sup>68</sup> Ayres, *supra* note 65, at 1015 n.278.

<sup>69</sup> See Health Insurance Reform: Standards of Electronic Transactions, 65 Fed. Reg. 50,312, 50,318 (Aug. 17, 2000) (to be codified at 45 C.F.R. pts. 160, 162) (reporting, in the preamble to the HIPAA Transactions Rule, that “[m]any commenters stated that exceptions [to federal preemption of state standards] in general should not be granted, saying that this is contrary to the idea of national standards”); see also Hill et al., *supra* note 56, at 534-37 (calling for preemption of state privacy law to promote development of interoperable data networks). *But see* Ko, *supra* note 67 (acknowledging this concern but concluding that HIPAA’s partial preemption framework has merit).

<sup>70</sup> Hill et al., *supra* note 56, at 555-94.

<sup>71</sup> Nat’l Fed’n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566, 2594 (2012) (holding that the individual health insurance mandate is a tax within Congress’s taxing powers, rather than relying on Commerce Clause arguments).

<sup>72</sup> See Stephen K. Phillips, *A Legal Research Guide to HIPAA*, 3 J. HEALTH & LIFE SCI. L. 134, 173-75 (2010) (summarizing various cases that challenged HIPAA or the HIPAA Privacy Rule). See generally *S.C. Med. Ass’n v. Thompson*, 327 F.3d 346 (4th Cir. 2003), *cert. denied*, 124 S. Ct. 464 (2003) (dismissing various constitutional claims).

<sup>73</sup> See generally CHARLES F. PHILLIPS, JR., *THE REGULATION OF PUBLIC UTILITIES: THEORY AND PRACTICE* (3d ed. 1993) (surveying the history of federal regulation of public utilities).

Health (“HITECH”) Act.<sup>74</sup> Congress declined to expand HIPAA’s preemption of state privacy law. Pragmatism counsels that HIPAA’s preemption provisions are not likely to change. Those who favor a more uniform legal framework to support large, interoperable public health data networks and public health uses of data must find a way to achieve these goals within the existing preemption framework. To paraphrase Donald Rumsfeld, “You go to war with the [HIPAA preemption provisions] you have, not the [provisions] you might want or wish to have at a later time.”<sup>75</sup> Accordingly, this Article takes a fresh look at HIPAA’s existing preemption provisions to check for tactical opportunities that earlier scouts may have overlooked.

## II. HIPAA’S PREEMPTION FRAMEWORK(S)

### A. *The Basic Structure of Preemption Analysis Under the Statute and the Privacy Rule*

In this Article, the term “HIPAA preemption provisions” refers to the statutory preemption provisions of HIPAA, located in section 1178 of the Social Security Act at 42 U.S.C. § 1320d-7. The HIPAA Privacy Rule’s own preemption provisions are at 42 C.F.R. §§ 160.201 – 160.205. The Privacy Rule’s § 160.203 states basic preemption rules that mirror the statutory provisions at 42 U.S.C. § 1320d-7.<sup>76</sup> As explained below, however, this “mirroring” is rather like looking through a glass darkly. Because the details of HIPAA’s preemption provisions are at issue in this discussion, Annex 1 reproduces the statute’s brief preemption provisions<sup>77</sup> in their entirety. For comparison, Annex 2 shows the corresponding § 160.203 of the HIPAA Privacy Rule.<sup>78</sup>

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<sup>74</sup> 42 U.S.C.A. §§ 17931-17940 (West 2010 & Supp. 2011).

<sup>75</sup> See Eric Schmitt, *Iraq-Bound Troops Confront Rumsfeld Over Lack of Armor*, N.Y. TIMES Dec. 8, 2004, <http://www.nytimes.com/2004/12/08/international/middleeast/08cnd-rumsfeld.html> (reporting Mr. Rumsfeld’s statement that “[y]ou go to war with the army you have, not the army you might want or wish to have at a later time”).

<sup>76</sup> See Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,480 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160, 164) (stating, in the preamble to the HIPAA Privacy Rule, that § 160.203 “proposed a general rule reflecting the statutory general rule and exceptions that generally mirrored the statutory language of the exceptions”).

<sup>77</sup> 42 U.S.C. § 1320d-7 (2006).

<sup>78</sup> 45 C.F.R. § 160.203 (2013); see also Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 78 Fed. Reg. 5566, 5690 (final rule, Jan. 25, 2013) (introducing no changes to 45 C.F.R. § 160.203 in a package of amendments to become effective March 26, 2013).



The statutory and regulatory preemption provisions are quite similar but they exhibit an obvious structural difference. Preemption analysis under the HIPAA statute is a three-pronged affair, whereas Privacy Rule preemption analysis only has two prongs. The statute includes:

- (1) a general preemption rule stated at 32 U.S.C. § 1320d-7(a)(1);
- (2) a set of exceptions or saving clauses listed in § 1320d-7(a)(2); and
- (3) two broad rules of construction in favor of certain public health laws and state regulatory reporting requirements, which appear at §§ 1370d-7(b) and (c).

The Privacy Rule has a simpler structure, as follows:

- (1) a general preemption rule in the opening clause of 45 C.F.R. § 160.203, and
- (2) a set of saving clauses listed in §§ 160.203(a) – (d).

Special protections for public health laws and state regulatory requirements, which appear as broad rules of construction in the HIPAA statute, are merely tacked onto the list of saving clauses in the Privacy Rule. This seemingly minor difference has profound implications for public health activities that require access to data or biospecimens.

#### **Annex 1. HIPAA's Statutory Preemption Provisions**

##### **Section 1178 of the Social Security Act, 42 U.S.C. Section 1320d-7**

##### **Section 1320d-7. Effect on State law**

###### **(a) General effect**

###### **(1) General rule**

Except as provided in paragraph (2), a provision or requirement under this part, or a standard or implementation specification adopted or established under sections 1320d-1 through 1320d-3 of this title [that is, the sections that authorize HHS to promulgate various regulations such as the HIPAA Privacy and Security Rules], shall supersede any contrary provision of State law, including a provision of State law that requires medical or health plan records (including

billing information) to be maintained or transmitted in written rather than electronic form.

(2) Exceptions

A provision or requirement under this part, or a standard or implementation specification adopted or established under sections 1320d-1 through 1320d-3 of this title, shall not supersede a contrary provision of State law, if the provision of State law—

(A) is a provision the Secretary determines—

(i) is necessary—

(I) to prevent fraud and abuse;

(II) to ensure appropriate State regulation of insurance and health plans;

(III) for State reporting on health care delivery or costs; or

(IV) for other purposes; or

(ii) addresses controlled substances; or

(B) subject to section 264(c)(2)<sup>79</sup> of the Health Insurance Portability and Accountability Act of 1996, relates to the privacy of individually identifiable health information.

(b) Public health

Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.

(c) State regulatory reporting

Nothing in this part shall limit the ability of a State to require a

<sup>79</sup> See Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, § 264(c)(2), 110 Stat. 1936 (1996) (codified as a note to 42 U.S.C. § 1320d-2) (stating a requirement that Congress imposed specifically on the HIPAA Privacy Rule that it “shall not supercede [sic] a contrary provision of State law, if the provision of State law imposes requirements, standards, or implementation specifications that are more stringent than the requirements, standards, or implementation specifications imposed under the [HIPAA Privacy Rule]”).

health plan to report, or to provide access to, information for management audits, financial audits, program monitoring and evaluation, facility licensure or certification, or individual licensure or certification.

**Annex 2: The HIPAA Privacy Rule's Preemption Rules  
45 C.F.R. Sec. 160.203**

**Part 160. General Administrative Requirements**

**Subpart B. Preemption of State Law**

**§ 160.203 General rule and exceptions**

A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law. This general rule applies, except if one or more of the following conditions is met:

- (a) A determination is made by the Secretary under § 160.204 that the provision of State law:
  - (1) Is necessary:
    - (i) To prevent fraud and abuse related to the provision of or payment for health care;
    - (ii) To ensure appropriate State regulation of insurance and health plans to the extent expressly authorized by statute or regulation;
    - (iii) For State reporting on health care delivery or costs; or
    - (iv) For purposes of serving a compelling need related to public health, safety, or welfare, and, if a standard, requirement, or implementation specification under part 164 of this subchapter is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served; or
  - (2) Has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in

21 U.S.C. 802), or that is deemed a controlled substance by State law.

- (b) The provision of State law relates to the privacy of individually identifiable health information and is more stringent than a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter.
- (c) The provision of State law, including State procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.
- (d) The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals.

#### B. *Common Elements of HIPAA Preemption Analysis*

The first prong of HIPAA preemption analysis is the same whether one is considering preemption under the HIPAA statute or under the Privacy Rule. This first step applies a general preemption rule: contrary state laws are preempted.<sup>80</sup> Questions during this phase of analysis include the types of state law that the general rule preempts (for example, does it merely preempt statutes and regulations, or is common law also preempted?) and the precise meaning of the word “contrary.” Through notice-and-comment rulemaking, HHS offered thoughtful proposals interpreting the meaning of statutory phrases such as “state law” and “contrary” and elicited public comments on how these terms should be interpreted.<sup>81</sup> Final regulations defining these terms appear at 45 C.F.R. § 160.202 and are an aid to applying both the statutory and regulatory preemption provisions.

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<sup>80</sup> 42 U.S.C. § 1320d-7(a)(1) (HIPAA statute); 45 C.F.R. § 160.203 (2013) (Privacy Rule).

<sup>81</sup> See Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 59,918, 59,995,997 (proposed Nov. 3, 1999) (to be codified at 45 C.F.R. pts. 160-164) (exploring various alternatives for defining the statutory phrases “state law,” “relates to the privacy of individually identifiable health information,” and “contrary” and offering regulatory language to interpret them).

The second prong of analysis applies the various saving clauses. Contrary state laws that appear preempted by the first prong of analysis may nevertheless be saved from preemption if they fit within one of the saving clauses. Some of the saving clauses appear in both the regulation and the statute.<sup>82</sup> With respect to these shared saving clauses, preemption analysis is basically the same whether one is considering preemption under the HIPAA statute or the Privacy Rule. The statutory exceptions in § 1320d-7(a)(2) provide three pathways for a state law to be saved from the general rule of preemption, and all three of these pathways have counterparts in the HIPAA Privacy Rule.

The first saving clause, in § 1320d-7(a)(2)(A)(i), requires a determination by the Secretary of HHS that the state law is necessary for various enumerated reasons or “for other purposes.” It is important to explain how this provision works because it becomes important in later discussion.<sup>83</sup> This pathway empowers the Secretary of HHS to make discretionary decisions not to preempt state laws that, in the Secretary’s judgment, are “necessary” for various reasons. Before enactment, this provision received considerable discussion and editing in Congress. HIPAA’s Administrative Simplification provisions had originated in the House of Representatives and had no counterparts in the Senate’s version of HIPAA. In the House bill, this saving clause protected state laws that the Secretary determined were “necessary to prevent fraud and abuse, or for other purposes.”<sup>84</sup> The conference agreement included the House’s saving clause but expanded it to save additional categories of state laws: those that the Secretary determines are necessary to prevent fraud and abuse, to ensure appropriate state regulation of insurance and health plans, for state reporting of healthcare delivery or costs, or for other purposes.<sup>85</sup> Thus, Congress thoughtfully enumerated several types of state law that it intended to save. Even with respect to these, Congress gave the Secretary a small amount of flexibility to override Congress by determining that a state law is not “necessary” to serve the enumerated purposes. Congress also gave the Secretary broad discretion to save additional categories of state law, again subject to a determination that the state law is necessary.

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<sup>82</sup> See 42 U.S.C. § 1320d-7(a)(2) (listing all of the statutory saving clauses); 45 C.F.R. § 160.203(a)-(b) (2013) (listing the subset of Privacy Rule saving clauses that corresponds to the statutory saving clauses).

<sup>83</sup> See discussion *infra* notes 138-139 and accompanying text.

<sup>84</sup> H.R. REP. NO. 104-496(I), at 261 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1865, 1984.

<sup>85</sup> H.R. CONF. REP. 104-736, at 268, (1996), *reprinted in* U.S.C.C.A.N. 1990, 2081.

The second saving clause, in § 1320d-7(a)(2)(A)(ii), saves state laws that the Secretary determines to be laws addressing controlled substances. This clause does not require the Secretary to determine that such laws are “necessary,” as does the preceding saving clause.<sup>86</sup> This difference limits the Secretary’s discretion to make decisions that affect the regulation of controlled substances. If she determines that a state law is aimed at addressing controlled substances, that state law is saved whether she believes the state law is necessary or not. In effect, Congress determined that state controlled-substances laws should be saved from federal preemption. Congress limited the Secretary’s role to determining whether particular state laws do or do not fit within the category of laws that the HIPAA statute protects.

The third saving clause, in § 1320d-7(a)(2)(B), saves state privacy laws that are contrary to, and more stringent than, the HIPAA Privacy Rule. This saving clause cross-references HIPAA’s section 264(c)(2), which is the section of HIPAA that authorized the Secretary to promulgate the Privacy Rule.<sup>87</sup> In section 264(c)(2), Congress directed that the Privacy Rule “shall not supercede [sic] a contrary provision of State law, if the provision of State law imposes requirements, standards, or implementation specifications that are more stringent than the requirements, standards, or implementation specifications imposed under the [HIPAA Privacy Rule].”<sup>88</sup> Available commentary on HIPAA preemption appears to have fixed its gaze on section 264(c)(2), isolating this section from its larger statutory context and treating it as the alpha and omega of HIPAA’s preemption provisions.<sup>89</sup> As seen in Annex 1, section 264(c)(2) is actually just one of many interacting parts within HIPAA’s statutory preemption provisions at 42 U.S.C. § 1320d-7.

Questions arising during the second prong of analysis include, for example, whether the Secretary has made the required determinations, what procedures and definitions should apply when making those determinations, and what does it mean for a state law to be “more stringent.”

Through rulemaking, HHS elaborated on the language of these exceptions as they apply to preemption under the HIPAA Privacy Rule. For example, the broad “for other purposes”<sup>90</sup> language of the

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<sup>86</sup> 42 U.S.C. § 1320d-7(a)(2)(A)(i).

<sup>87</sup> See Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, § 264(c)(2), 110 Stat. 1936 (1996) (codified as a note to 42 U.S.C. § 1320d-2).

<sup>88</sup> *Id.* § 264(c)(2).

<sup>89</sup> 42 U.S.C. § 1320d-7.

<sup>90</sup> *Id.* § 1320d-7(a)(2)(A)(i)(IV).

statute was interpreted to mean that the Secretary can approve exceptions (in other words, the Secretary can decide to save state laws from federal preemption) “[f]or purposes of serving a compelling need related to public health, safety, or welfare.”<sup>91</sup> When doing so, the Secretary must determine that “the intrusion into privacy is warranted when balanced against the need to be served” if the use presents issues under the HIPAA Privacy Rule.<sup>92</sup> The Privacy Rule also spells out procedures for seeking these Secretarial determinations, and it explains the duration of such exceptions and grounds for their revocation.<sup>93</sup> Once again, HHS interpreted the statute through a thoughtful rulemaking process that elicited public comments on the agency’s carefully reasoned proposals.<sup>94</sup>

Up to this point, there is no real difference in how the HIPAA statute and the Privacy Rule handle preemption of state laws: the regulation faithfully restates and clarifies the corresponding statutory provisions. Beyond this point, however, a major difference emerges. The Privacy Rule expands the second-prong analysis of saving clauses by adding two additional saving clauses. These protect certain types of state public health laws<sup>95</sup> and state regulatory reporting requirements<sup>96</sup> and prevent the HIPAA Privacy Rule from interfering with them. HIPAA’s statutory preemption scheme protects these same types of state public health laws and state regulatory reporting requirements, but does so through a different mechanism that amounts to a third prong of statutory preemption analysis.

### C. *The Third Prong of Statutory Preemption Analysis*

The Privacy Rule and HIPAA statute have two remaining pairs of provisions that resemble one another. These include a pair of public health provisions<sup>97</sup> and a pair of provisions relating to state regulatory

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<sup>91</sup> 45 C.F.R. § 160.203(a)(1)(iv) (2013).

<sup>92</sup> *Id.*

<sup>93</sup> *Id.* §§ 160.204-160.205.

<sup>94</sup> See generally Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 59,918 (proposed Nov. 3, 1999) (to be codified at 45 C.F.R. pts. 160-164) (proposing the HIPAA Privacy Rule and providing a detailed preamble explaining the agency’s reasoning and approaches to issues that arose while developing the proposal).

<sup>95</sup> 45 C.F.R. § 160.203(c).

<sup>96</sup> *Id.* § 160.203(d).

<sup>97</sup> See 42 U.S.C. § 1320d-7(b) (2006) (HIPAA statute); 45 C.F.R. § 160.203(c) (Privacy Rule).

reporting requirements.<sup>98</sup> For brevity, and because public health is the subject of this Article, the remaining discussion focuses on the first of these pairs. The public health provisions at § 160.203(c) of the Privacy Rule and § 1320d-7(b) of the statute share a lot of the same wording. The Privacy Rule provides:

This general rule applies, except if one or more of the following conditions is met:<sup>99</sup>

. . .

- (c) The provision of State law, including State procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.<sup>100</sup>

In contrast, the HIPAA statute states:

- (b) Public health

Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.<sup>101</sup>

Both extend special protections to laws that provide for a list of enumerated public health activities that includes the conduct of “public health surveillance, investigation, or intervention.”<sup>102</sup> With that, the similarity ends. The statute and Privacy Rule protect such laws through entirely different mechanisms.

The Privacy Rule’s provision at § 160.203(c) is merely an additional exception to the general rule of preemption. It tacks one more saving clause, in favor of state public health laws, onto the list of saving clauses that precede it. The statutory provision at 42 U.S.C. § 1320d-7(b), in contrast, is set apart from the saving clauses listed immediately before it in § 1320d-7(a)(2). Section 1320d-7(b) appears under a separate heading (“Public health”) and stands completely

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<sup>98</sup> See 42 U.S.C. § 1320d-7(c) (HIPAA statute); 45 C.F.R. § 160.203(d) (Privacy Rule).

<sup>99</sup> 45 C.F.R. § 160.203.

<sup>100</sup> *Id.* § 160.203(c).

<sup>101</sup> 42 U.S.C. § 1320d-7(b).

<sup>102</sup> *Id.* § 1320d-7(b); 45 C.F.R. § 160.203(c).



separate from, and on an equal footing with, § 1320d-7(a), which states the general preemption rule and its exceptions. The whole-text canon requires that, when interpreting a statute, one should “consider the entire text, in view of its structure and of the physical and logical relation of its many parts,” and “[c]ontext is a primary determinant of meaning.”<sup>103</sup> While not always dispositive, “title[s] and headings are permissible indicators of meaning.”<sup>104</sup> These factors strongly suggest that § 1320d-7(b) is not just another run-of-the-mill-saving clause.

This raises a question: if 42 U.S.C. § 1320d-7(b) is not a saving clause, what is it? Before answering that question, it is important to note a second major difference: The Privacy Rule’s § 160.203(c) affords special protection only to *state* laws that provide for the enumerated public health activities. The corresponding statutory provision at § 1320d-7(b) affords special protection to “any law” that provides for the same enumerated public health activities. Here again, context matters,<sup>105</sup> as do subtle variations in wording.<sup>106</sup> Section 1320d-7(b) is sandwiched between two provisions, 1320d-7(a)(2) and 1320d-7(c), in which Congress carefully used the phrase “State law” to refer to state law. When interpreting a statute, “a material variation in terms suggests a variation in meaning.”<sup>107</sup> Congress’s choice of the phrase “any law” in § 1320d-7(b) must be presumed deliberate. Congress extended the special protections of § 1320d-7(b) to federal public health laws as well as state public health laws.<sup>108</sup>

This presents another mystery: Why would Congress insert wording to save *federal* laws from preemption (or, more correctly, supersession) in § 1320d-7, which bears the heading, “Effect on *State* law”?<sup>109</sup> When Congress sets out to discuss a new law’s impact on both state and federal laws, Congress typically words its headings differently.<sup>110</sup> The heading of § 1320d-7 clearly signals that Congress is

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<sup>103</sup> ANTONIN SCALIA & BRYAN A. GARNER, *READING LAW: THE INTERPRETATION OF LEGAL TEXTS* 167 (2012).

<sup>104</sup> *Id.* at 221.

<sup>105</sup> *Id.* at 167.

<sup>106</sup> *See id.* at 170 (discussing the presumption of consistent uses).

<sup>107</sup> *Id.*

<sup>108</sup> The phrase “any law” also may include international and municipal public health laws, but this Article only considers the impact of this provision on access to data and biospecimens for enumerated public health activities authorized by state and federal laws.

<sup>109</sup> 42 U.S.C. § 1320d-7 (2006 & Supp. V 2011) (emphasis added).

<sup>110</sup> *Compare* 29 U.S.C. § 1144 (2006 & Supp. V 2011) (addressing ERISA preemption of state law in §§ 1144(a)-(c) and ERISA’s relationship to other federal laws in § 1144(d) and bearing the title “Other laws”), *with* 42 U.S.C. § 1320d-7

addressing impacts on state law and not federal law. Moreover, Congress addressed HIPAA's impact on various other federal laws elsewhere in the statute and did not need to do so here.<sup>111</sup> If the public health provision at § 1320d-7(b) were merely a saving clause (that is, a clause that protects other laws from being displaced by the substantive requirements of HIPAA and its implementing regulations), Congress's use of the phrase "any law" (as opposed to "State law") would make no sense in this provision.

The solution to this mystery is that 42 U.S.C. § 1320d-7(b) is not a saving clause. Rather, it is a rule of construction that, among other things, limits the reach of the saving clauses that appear immediately before it in the statute. Section 1320d-7(b) begins with superordinating, mandatory language ("Nothing in this part shall be construed . . .") that sets the words that follow ahead of conflicting statutory provisions in the event of a clash.<sup>112</sup> Section 1320d-7(b) is a broad rule of construction that directs judges, regulators, and all others to make sure to protect laws that provide for the enumerated public health activities. Its mention of "any law" very clearly attempts to protect laws that provide for the enumerated public health activities from *something* . . . but from what? That *something*, it turns out, is privacy laws.<sup>113</sup>

Section 1320d-7(b) addresses the possibility that state and federal *privacy* laws may hinder the effective operation of state and federal *public health* laws. Section 1320d-7(b) expresses the balance that Congress wants regulators and judges to strike in the event of such a clash. The basic directive of § 1320d-7(b) is that privacy laws — not just the Privacy Rule, but any state privacy laws that the Privacy Rule fails to preempt — must give way if they interfere with certain very important public health laws. This explains why it makes sense for

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(bearing the title, "Effect on State Law").

<sup>111</sup> See Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 59,918, 59,999 (proposed Nov. 3, 1999) (to be codified at 45 C.F.R. pts. 160-164) (discussing, in the preamble to the proposed HIPAA Privacy Rule, definitional and other sections of the HIPAA statute that expressly subject certain federal programs to regulations promulgated under the HIPAA statute and noting that "Congress's express inclusion of certain federal programs in the statute . . . has significance, as it constitutes an express Congressional statement that the HIPAA standards and implementation specifications apply to these programs"); see also *id.* at 59,999-60,002 (providing a carefully reasoned analysis, based on the statutory text and legislative history, of HIPAA's impact on various other federal statutes and regulations).

<sup>112</sup> See generally SCALIA & GARNER, *supra* note 103, at 126-28 (discussing subordinating and superordinating language in statutory texts).

<sup>113</sup> See discussion *infra* in next paragraphs.

Congress to have included this provision as part of § 1320d-7, which addresses HIPAA's "Effect on State law." The directive in § 1320d-7(b) does affect state laws — but its effect may be to preempt them as well as to save them. A state privacy law that otherwise would be saved from preemption by HIPAA's saving clauses may be preempted under § 1320d-7(b), if saving the state privacy law would "limit the authority, power, or procedures established under any law" that provides for the enumerated public health activities. Section 1320d-7(b) limits the application of the saving clauses of § 1320d-7(a)(2).

Section 1320d-7(b) is unambiguous in its basic directive and leaves no room for agency interpretation. The phrase "any law" means "any law." The phrase "nothing in this part" means "nothing in this part." The "part" to which this phrase refers can easily be determined by looking at the larger statutory context in which § 1320d-7(b) appears. Section 262 of the HIPAA statute enacted a new Part C of title XI of the Social Security Act,<sup>114</sup> which includes the Administrative Simplification provisions that HIPAA inserted at 42 U.S.C. §§ 1320d – 1320d-8.<sup>115</sup> Section 1320d-7 is one piece of these Part C Administrative Simplification provisions. Section 1320d-7(b), when it refers to "this part," is referring to *them*. It is referring to the whole of the Part C Administrative Simplification provisions. Nothing *in them* shall get in the way of any law — state or federal — that serves various enumerated public health purposes.

The Administrative Simplification provisions include *inter alia* the saving clauses listed in § 1320d-7(a)(2). These saving clauses (like all other aspects of the Administrative Simplification provisions and any regulations promulgated pursuant the Administrative Simplification provisions) must not "be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention."<sup>116</sup>

The only potential ambiguities in § 1320d-7(b) concern the scope of public health laws it aims to protect. For example, does the term "disease" only include infectious and malignant diseases or does it also include obesity and depression? Does the phrase "public health

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<sup>114</sup> 42 U.S.C. §§ 1320d to 1320d-8.

<sup>115</sup> 42 U.S.C. §§ 1320d to 1320d-8; see Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 262 (1996). See generally Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 59,918, 59,920 (discussing HIPAA's Administrative Simplification provisions in the preamble to the proposed HIPAA Privacy Rule).

<sup>116</sup> 42 U.S.C. § 1320d-7(b).

investigation” include investigations that produce generalizable knowledge (as it seems to do) or does it only include nongeneralizable studies that fit within the traditional subcategory of “public health practice”?<sup>117</sup> There is room for a regulator to interpret the scope of public health laws that § 1320d-7(b) protects, but there is no room to interpret this provision’s basic directive which is unambiguous.

The House Committee on Ways and Means, in its report on the HIPAA House bill, explained that § 1320d-7(b) has the effect just described: that is, it limits the application of HIPAA’s other preemption provisions.<sup>118</sup> As already noted, HIPAA’s Administrative Simplification provisions originated in the House bill, which included HIPAA’s preemption provisions as a new section 1178 of the Social Security Act to be codified at 42 U.S.C. § 1320d-7. The conference agreement subsequently incorporated the House bill’s preemption provisions, with various changes, into the enacted HIPAA statute. However, the conference agreement made no changes in the House’s rule of construction and accepted it without further discussion.<sup>119</sup> The House bill’s rule of construction was thus identical to the enacted language of 42 U.S.C. § 1320d-7(b). Because the conferees did not discuss this provision, the House Report offers the only explanation of what Congress thought it meant.<sup>120</sup>

In summarizing how the new preemption provisions would work, the House Report began by stating, “The intent of this section [Section 1178 of the Social Security Act] is to ensure that state privacy laws that are more stringent than the requirements and standards contained

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<sup>117</sup> See generally JAMES G. HODGE, JR., & LAWRENCE O. GOSTIN, COUNCIL OF STATE & TERRITORIAL EPIDEMIOLOGISTS, PUBLIC HEALTH PRACTICE VS. RESEARCH 7-9 (2004), available at <http://www.cste.org/pdffiles/newpdffiles/CSTEPHResRptHodgeFinal.5.24.04.pdf> (defining and distinguishing the traditional categories of public health practice and public health research).

<sup>118</sup> See H.R. REP. NO. 104-496, at 103 (1996), reprinted in 1996 U.S.C.C.A.N. 1865, 1903; see also discussion *infra* Part II.C (summarizing the House Report’s discussion).

<sup>119</sup> See Social Security Act § 1178(b), 42 U.S.C. § 1320d-7(b)); H.R. REP. NO. 104-496, at 260-61 (1996) (showing the text of the House bill’s HIPAA preemption provisions at § 1178 of the Social Security Act, which included a rule of construction that stated “[n]othing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention”).

<sup>120</sup> See H.R. REP. NO. 104-736, at 268-69 (1996), reprinted in 1996 U.S.C.C.A.N. 1990, 2081-82 (addressing other issues with HIPAA’s preemption provisions but recording no concerns about the rule of construction at section 1178(b) of the Social Security Act, 42 U.S.C. § 1320d-7(b)).

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in the bill are not superseded.”<sup>121</sup> The House Report then gave a brief summary of the section’s general preemption rule and its saving clauses, and concluded, “Nothing in this section would be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth or death, public health surveillance, or public health investigation or intervention.”<sup>122</sup>

The Report’s use of “this section” in that last sentence is significant. It demonstrates that legislators expected the rule of construction to limit application of the section in which it appears — that is, to limit application of HIPAA’s other preemption provisions. Another significant point is that the House Report saw no inconsistency between the House’s broad intent (which was to avoid preemption of more stringent state privacy laws) and its inclusion of a rule of construction that might very well preempt such laws if they interfered with the enumerated public health activities. Congress clearly intended to protect more stringent state laws, but only up to a point. That point would be reached if more stringent state privacy laws interfered with the enumerated public health activities, which Congress was determined to protect.

Although the Conference Report did not discuss the rule of construction, it strongly emphasized the importance of ensuring access to data for use in informational studies that benefit the public as a whole.<sup>123</sup> The following statement appears at the end of the conferee’s discussion of section 1173 of the Social Security Act,<sup>124</sup> which is the major section authorizing the Secretary of HHS to establish standards and regulations under the HIPAA statute:

The conferees recognize that certain uses of individually identifiable information are appropriate, and do not compromise the privacy of an individual. Examples of such use of information include the transfer of information when making referrals from primary care to specialty care, and *the transfer of information from a health plan to an organization for the sole purpose of conducting health care-related research. As health plans and providers continue to focus on outcomes research*

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<sup>121</sup> H.R. REP. NO. 104-496, at 103 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1865, 1903.

<sup>122</sup> *Id.*

<sup>123</sup> See H.R. REP. NO. 104-736, at 268, *reprinted in* 1996 U.S.C.C.A.N. 1990, 2081.

<sup>124</sup> 42 U.S.C. § 1320d-2.

*and innovation, it is important that the exchange and aggregated use of health care data be allowed.*<sup>125</sup>

Congress was committed to protecting both privacy and data access.

To balance these potentially conflicting objectives, HIPAA's statutory preemption framework adopts the same three-pronged complexity that elsewhere graces ERISA's preemption provisions.<sup>126</sup> The HIPAA and ERISA preemption provisions, while differing in many particulars, share a broad structural similarity: First, they establish a baseline rule that the federal statute preempts state law.<sup>127</sup> For this purpose, ERISA employs broad field preemption language<sup>128</sup> whereas HIPAA embraces a more modest conflict preemption concept that only preempts "contrary" state law.<sup>129</sup> This difference — albeit a major one — is not important to the present discussion. Second, both statutes expressly provide exceptions to their preemption rules.<sup>130</sup> These exceptions are enumerated in saving clauses that protect specific categories of state law from federal preemption.<sup>131</sup> Third, there are

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<sup>125</sup> H.R. REP. 104-736, at 265, *reprinted in* 1996 U.S.C.C.A.N. 1990, 2078 (emphasis added).

<sup>126</sup> *Compare* 29 U.S.C. §§ 1144(a)-(d) (2006 & Supp. V 2011) (providing a three-tiered preemption provision as discussed *infra* notes 130-132 and accompanying text), *with* 42 U.S.C. § 1320d-7 (providing a three-tiered preemption provision as discussed *supra* Part II).

<sup>127</sup> *Compare* 29 U.S.C. § 1144(a) (codifying the baseline preemption rule stated in ERISA's § 514(a)), *with* 42 U.S.C. § 1320d-7(a)(1) (codifying HIPAA's general preemption rule).

<sup>128</sup> *See* 29 U.S.C. § 1144(a) (providing for ERISA preemption of "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan"); *see also* Rosenbaum et al., *supra* note 15, at 13 (commenting on the breadth of ERISA's preemption language, which "set out to preempt all state laws that 'relate to' employee benefit plans covered by ERISA," with various exceptions).

<sup>129</sup> *See* 42 U.S.C. § 1320d-7(a)(1) (superseding "any contrary provision of State law"); *see also* 45 C.F.R. § 160.202 (2013) (defining "contrary" to mean: "(1) A covered entity would find it impossible to comply with both the State and federal requirements; or (2) The provision of State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of part C of title XI of the Act, section 264 of Public Law 104-191, or section 13402 of Public Law 111-5, as applicable").

<sup>130</sup> *See* 29 U.S.C. § 1144(a) (prefacing ERISA's general preemption rule with, "[e]xcept as provided in subsection (b) of this section"); 42 U.S.C. § 1320d-7(a)(1) (prefacing HIPAA's general preemption rule with, "[e]xcept as provided in paragraph (2)").

<sup>131</sup> *See, e.g.,* 29 U.S.C. § 1144(b)(2)(A) (saving state laws that regulate insurance, banking, or securities from ERISA preemption); 29 U.S.C. § 1144(b)(4) (saving generally applicable state criminal law from ERISA preemption); 29 U.S.C. § 1144(b)(5)(A) (saving a specific Hawaii law from ERISA preemption); 42 U.S.C. § 1320d-7(a)(2) (saving certain provisions of state law from HIPAA preemption and

exceptions to the exceptions. These are rules of construction that limit application of the saving clauses, thus reinstating federal preemption of state law in certain narrow contexts.<sup>132</sup> State laws that may have seemed “saved” after the second prong of analysis may nevertheless be preempted in these specific contexts. Analyzing express preemption under the HIPAA and ERISA statutes is thus a three-step process.

In a battle between a statutory saving clause and § 1320d-7(b), the latter provision prevails because of its superordinating language.<sup>133</sup> In ordinary contexts, it remains true that the statute calls for a federal floor of privacy protections and leaves states free to set more stringent privacy standards. But the statute alters this rule in one specific circumstance. State laws that are more stringent than the HIPAA Privacy Rule — and thus saved by the exception at 42 U.S.C. § 1320d-7(a)(2)(B) — are preempted by § 1320d-7(b) if they invalidate or limit laws that provide for the enumerated public health activities. In this one circumstance, then, HIPAA preempts more stringent state privacy laws. When this occurs, the HIPAA Privacy Rule effectively sets both a floor and a ceiling on the privacy standards that govern disclosure and use of data and biospecimens for the enumerated public health activities.

### III. HOW THE REGULATORY AND STATUTORY PREEMPTION PROVISIONS INTERRELATE

As demonstrated in Part II, the HIPAA Privacy Rule has no third prong in its preemption framework and differs materially from the statute it purports to implement. This discussion explores the impact of that discrepancy. The critical question is whether the Privacy Rule’s public health saving clause displaces, or instead coexists with, the stronger statutory preemption provision at § 1320d-7(b).<sup>134</sup> This translates into two subquestions: (1) Is the Privacy Rule’s weaker provision entitled to deference as an agency interpretation that, in

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listing various specific exceptions to HIPAA’s general rule of preemption).

<sup>132</sup> See, e.g., 29 U.S.C. § 1144(b)(2)(B) (stating ERISA’s so-called “deemer” clause, which keeps states from “deeming” self-funded employer-sponsored health plans to be “insurers” that are subject to state law); 42 U.S.C. § 1320d-7(b) (stating a broad principle of law that, as discussed *supra* in this Article, disables HIPAA’s § 1320d-7(a)(2) saving clauses in situations where the application of non-preempted state laws would limit the enumerated public health activities); *id.* § 1320d-7(c) (stating a similar rule of construction that protects enumerated state regulatory reporting requirements).

<sup>133</sup> See SCALIA & GARNER, *supra* note 103, at 126-28 (discussing the effect of subordinating and superordinating language in statutory texts).

<sup>134</sup> 45 C.F.R. § 160.203(c) (2013).

effect, establishes the meaning of the stronger statutory preemption provision? (2) Alternatively, is the Privacy Rule's weaker provision something other than a statutory interpretation — a narrow application of a broad statutory rule, perhaps, or a studious avoidance of an issue — in which case the statute continues to have its own, independent meaning that supplements the regulation?

The public health provision at § 1320d-7(b) of the HIPAA statute is a muscular provision that does considerably more work than the puny little public health saving clause at § 160.203(c) of the HIPAA Privacy Rule. The Privacy Rule's saving clause merely prevents the substantive requirements of the HIPAA Privacy Rule from interfering with state laws that provide for the enumerated public health activities. That is all it does. Section 1320d-7(b) protects state and federal laws that provide for the enumerated public health activities from a broader range of threats. These threats include:

- the risk that the Administrative Simplification provisions themselves could be construed in a way that invalidates or limits the protected state and federal public health laws,
- the risk that substantive regulations promulgated under the Administrative Simplification provision, such as the HIPAA Privacy Rule, could be construed in a way that limits or invalidates the protected state and federal public health laws, and
- the risk that saving clauses in the Administrative Simplification provisions (and in regulations promulgated pursuant to the Administrative Simplification provisions) could be construed in a way that saves state privacy laws that invalidate or limit the protected state or federal public health laws.

Section 1320d-7(b) includes the same protection that the Privacy Rule's § 160.203(c) saving clause provides: it prevents the HIPAA Privacy Rule from interfering with state laws that provide for the enumerated public health activities. But § 1320d-7(b) does not stop there. It supplies a whole array of additional protections in favor of state and federal public health laws.

#### A. *Privacy Rule Preemption as a Statutory Interpretation*

Let us assume as an aid to discussion that HHS intended for § 160.203(c) of the Privacy Rule to interpret — that is, to decide the meaning of — the rule of construction at § 1320d-7(b) of the HIPAA



statute. The framework of deference analysis under *Chevron, U.S.A., Inc. v. Natural Res. Def. Council*<sup>135</sup> and *United States v. Mead Corp.*<sup>136</sup> views agencies, rather than courts, as the most appropriate bodies to interpret the meaning of agencies' own enabling statutes. Under this framework, courts are expected to apply *Chevron's* deferential two-step analysis<sup>137</sup> when reviewing statutory interpretations that an agency has expressed in regulations that the agency promulgated via notice-and-comment proceedings pursuant to a Congressional delegation of lawmaking authority to the agency.<sup>138</sup> Under *Mead*, a statutory interpretation embedded in the HIPAA Privacy Rule seemingly would be *Chevron*-eligible.<sup>139</sup>

There are nuances, however, and one of them concerns HHS's delegated authority to make choices about preemption. Congress clearly delegated authority for HHS to promulgate substantive standards of conduct, such as the HIPAA Privacy and Security Rules, but this does not necessarily mean that Congress delegated authority for HHS to decide the preemptive impact of its regulations.<sup>140</sup> The statute, at 42 U.S.C. § 1320d-7(a)(2)(A), does grant authority for the Secretary of HHS to determine whether specific provisions of state law are saved from HIPAA preemption. However, Congress constrained this authority in various ways and required the Secretary to apply it on a provision-of-state-law-by-provision-of-state-law basis.<sup>141</sup> A court might well conclude that 42 U.S.C. § 1320d-7(a)(2)(A) expresses the full extent of the Secretary's delegated authority to decide questions of preemption, and that Congress never delegated authority for the Secretary to make broad rules interpreting the meaning of HIPAA's

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<sup>135</sup> *Chevron, U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837 (1984).

<sup>136</sup> *United States v. Mead Corp.*, 533 U.S. 218 (2001).

<sup>137</sup> See *Chevron*, 467 U.S. at 842-43 (calling for courts, as the first step, to assess whether Congress has "directly spoken to the precise question at issue" and, if so, to be guided by the statute or, if not, to then inquire into whether the "agency's answer is based on a permissible [i.e., not necessarily the best] construction of the statute" and, if so, to defer to it).

<sup>138</sup> *Mead*, 533 U.S. at 226-27, 230-33 (2001); see also *Gonzales v. Oregon*, 546 U.S. 243, 259 (2006).

<sup>139</sup> See *Mead*, 533 U.S. at 226-27, 230-33.

<sup>140</sup> See, e.g., *Gonzales*, 546 U.S. at 263 (citing *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649-50 (1990)) (stating the view that a general delegation of authority to an agency does not include "the authority to decide the pre-emptive scope of the federal statute" unless the statute provides additional clarification of the latter intent); see also Thomas W. Merrill, *Preemption and Institutional Choice*, 102 NW. U. L. REV. 727, 768-69 (2008) (construing this passage to mean that a separate delegation of authority to decide the statute's preemptive scope needs to be evident in the statute).

<sup>141</sup> See discussion *supra* notes 83-85 and accompanying text.

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statutory preemption provisions. Eskridge and Baer's empirical study found that the Supreme Court follows *Chevron's* framework in only about one-fourth of the cases where it seemingly would be applicable under *Mead*.<sup>142</sup> It is far from certain that the Privacy Rule's interpretation of HIPAA's preemption provisions would receive *Chevron* deference if the agency sought *Chevron* deference.

Assume, however, that *Chevron* applies: how would the Privacy Rule's preemption provisions fare? The provisions at §§ 160.203(a) and (b) of the Privacy Rule simply restate the corresponding statutory provisions and clarify details; they are well within the bounds of permissible statutory interpretation. In contrast, the Privacy Rule's public health saving clause at 160.203(c) is materially different from the rule of construction at 42 U.S.C. § 1320d-7(b). At step one of *Chevron* analysis, courts inquire whether Congress has spoken directly to the issue.<sup>143</sup> Looking at § 1320d-7(b), courts will discover that Congress spoke very directly: the rule of construction binds courts as well as the agency, and courts can be expected to understand it and follow it. If the agency intended Privacy Rule's § 160.203(b) to serve as an interpretation of this statute, then the interpretation itself violates the statute. "Nothing in this part shall be construed . . ." means, among other things, that the agency shall not construe the statute's broad rule of construction to be a mere saving clause for state public health laws. Construing it that way has the effect of saving more stringent state privacy laws even when they interfere with the enumerated public health activities, and the rule of construction forbids that. Even under *Chevron*, courts do not defer to agency interpretations that are contrary to statute.<sup>144</sup> Agencies are free to interpret an ambiguous statute,<sup>145</sup> but § 1320d-7(b) offers very little ambiguity for an agency to interpret. It is crystal clear in its basic directive to protect any law that provides for the enumerated public health activities.<sup>146</sup> It leaves room only for an agency to interpret the precise scope of public health activities that are protected.<sup>147</sup> Even under a deferential *Chevron* analysis, the Privacy Rule's § 160.203(b)

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<sup>142</sup> Eskridge & Baer, *supra* note 7, at 1124-25.

<sup>143</sup> See *supra* note 137.

<sup>144</sup> *Chevron, U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 844 (1984).

<sup>145</sup> *Id.* at 842-43 (calling for courts to be guided by the statute if Congress has "directly spoken to the precise question at issue" but recognizing that there is room for agencies to interpret a statute that is ambiguous).

<sup>146</sup> See *supra* notes 108, 114 and accompanying text.

<sup>147</sup> *Id.*

would not stand up as a permissible interpretation of 42 U.S.C. § 1320d-7(b).

In the alternative, if courts choose not to apply *Chevron*, they would apply a less deferential standard of review. Under the standard articulated in *Skidmore v. Swift & Co.*,<sup>148</sup> which the Supreme Court followed in *Mead*,<sup>149</sup> an agency interpretation receives “respect proportional to its power to persuade.”<sup>150</sup> Courts consider the “thoroughness, logic, and expertness” of the agency’s interpretation when deciding whether to defer to it.<sup>151</sup> *Skidmore* analysis is generally “not as generous to the agency as *Chevron*’s reasonableness standard.”<sup>152</sup> Still, it is conceivable that § 160.203 of the Privacy Rule might stand up to *Skidmore* scrutiny if HHS offered a logical, thorough, and persuasive account of why the HIPAA statute’s rule of construction needs to be interpreted as a mere saving clause for state public health laws.

Unfortunately, HHS offered no such account. HHS promulgated the Privacy Rule’s preemption provisions as part of rulemaking proceedings that fill 500 pages in the Federal Register.<sup>153</sup> Carefully reasoned preambles to the proposed and final Privacy Rule offer thorough analysis of many of the issues the agency faced while developing its regulations. However, the agency’s analysis is uncharacteristically curt and shoddy with respect to the statutory rule of construction at 42 U.S.C. § 1320d-7(b). The preamble to the proposed Privacy Rule summarized HIPAA’s various statutory preemption provisions but, referring to the two rules of construction,<sup>154</sup> simply said: “There also are certain areas of State law (generally relating to public health and oversight of health plans) that are explicitly carved out of the general rule of preemption and addressed separately.”<sup>155</sup>

Later in that preamble, the agency presumed without discussion that the rule of construction in § 1320d-7(b) is merely a saving clause that

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<sup>148</sup> *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944).

<sup>149</sup> *United States v. Mead Corp.*, 533 U.S. 218, 235 (2001).

<sup>150</sup> *Id.* (citing *Skidmore*, 323 U.S. at 140).

<sup>151</sup> *Id.*

<sup>152</sup> Eskridge & Baer, *supra* note 7, at 1109.

<sup>153</sup> See Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 59,918 (proposed Nov. 3, 1998) (presenting the proposed Privacy Rule in 146 pages); Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,826 (Dec. 28, 2000) (presenting the final HIPAA Privacy Rule in 364 pages).

<sup>154</sup> 42 U.S.C. §§ 1320d-7(b)-(c) (2012).

<sup>155</sup> Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. at 59,922.

stands on equal footing with the other statutory saving clauses expressed at § 1320d-7(a)(2).<sup>156</sup> The agency offered reasoned analyses of many preemption-related questions (such as the meanings of “contrary,” “State law,” and “more stringent”),<sup>157</sup> but merely repeated that § 1320d-7(b) is a “carve-out.”<sup>158</sup> At one point, the agency evinced a bit of shakiness about whether § 1320d-7(b) is, in fact, a “carve-out”<sup>159</sup> but seemed to regard the term “carve-out” as so clear and obvious that there was no need explain what the agency thought it meant. The agency clarified that existing *and future* state laws fit within the carve-out, without ever discussing what a carve-out is.<sup>160</sup>

The agency never inquired whether the phrase “any law” in § 1320d-7(b) may possibly encompass federal as well as state law.<sup>161</sup> Its only engagement with the statutory phrase, “authority, power, or procedures established under any law,” focused on interpreting the word “procedures,” which the agency construed as including administrative regulations and guidelines. As a statutory interpretation, the agency’s handling of the rule of construction at 42 U.S.C. § 1320d-7(b) is reminiscent of a tennis player who deliberately taps the ball into the net. The agency never seriously engaged with the statutory text. It is as if the agency “carved out” § 1320d-7(b) and chose not to read it. Under *Skidmore*, this analysis would receive respect in proportion to its “power to persuade” — that is, very little.<sup>162</sup>

Whether they apply a *Chevron* or *Skidmore* analysis, courts are likely to conclude that the HIPAA Privacy Rule *does not* establish the meaning of HIPAA’s statutory rule of construction at 42 U.S.C. § 1320d-7(b). The statutory rule of construction at 42 U.S.C. § 1320d-7(b) is undiminished and remains in full force after promulgation of

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<sup>156</sup> See *id.* at 59,226 (stating that “[t]he HIPAA also provides that standards issued by the Secretary will not supercede [sic] certain other State laws, including: State laws relating to reporting of disease or injury, child abuse, birth or death, public health surveillance, or public health investigation or intervention; State regulatory reporting; State laws which the Secretary finds are necessary to prevent fraud and abuse, to ensure appropriate State regulation of insurance, for State reporting on health care delivery or costs, or for other purposes; or, State laws which the Secretary finds address controlled substances”).

<sup>157</sup> *Id.* at 59,994-99.

<sup>158</sup> *Id.* at 59,998.

<sup>159</sup> *Id.* (noting that “[t]his section *appears* to carve out an area over which the States have traditionally exercised oversight and authority”) (emphasis added).

<sup>160</sup> *Id.*

<sup>161</sup> *Id.*

<sup>162</sup> See *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944).

the HIPAA Privacy Rule. Section 1320d-7(b) stands alongside the Privacy Rule's less preemptive provisions and limits application of the Privacy Rule's saving clauses. The preemption provisions of the HIPAA statute and Privacy Rule coexist in the following relationship:

- Prong one of preemption analysis applies the statute's general preemption rule, as interpreted by the HIPAA Privacy Rule. This stage of the analysis identifies state laws that are apparently preempted by the general rule. These "apparently preempted" state laws require further analysis in prong two.
- Prong two begins by applying the shared saving clauses that appear in both the statute and the regulation. For these, the Privacy Rule interprets the statute. Prong two then continues by applying the Privacy Rule's additional two saving clauses; they are not contrary to the statute but leave some of its work unfinished. That unfinished statutory business is deferred for possible analysis in prong three. At the end of prong two, some state laws that were preempted after prong one may appear saved.
- There is only one circumstance where the third prong of preemption analysis comes into play. This circumstance occurs when the Privacy Rule saves a more stringent state privacy law that interferes with public health access to data and biospecimens. In this case, the two-pronged Privacy Rule analysis is not the end of the preemption inquiry, which also must consider the HIPAA statute itself (in prong three). If the state law interferes with the enumerated public health activities, § 1320d-7(b) of the HIPAA statute will preempt it. This third prong of analysis is necessary only when Privacy Rule preemption analysis (prongs one and two above) concludes that a state privacy law is *not* preempted. If the Privacy Rule's two-prong preemption analysis finds that a state law is preempted, there is no need to conduct a statutory preemption analysis because doing so could only confirm that same result.

B. *Privacy Rule Preemption as an Assessment of Institutional Competence*

The fact of a discrepancy between the statutory and regulatory preemption provisions does not imply that there is anything wrong with the Privacy Rule. The regulations do not cover as much ground as the statute does, but this is not necessarily a defect in the regulations and, indeed, it arguably is a virtue. A plausible view of the Privacy Rule's preemption provisions is that they reflect an exercise of regulatory modesty and restraint on a question that proved deeply controversial as the Privacy Rule was being developed.<sup>163</sup> That question was: "Is there any context in which HIPAA preempts state privacy laws that offer individuals *stronger* protections than they enjoy under the HIPAA Privacy Rule?" The Privacy Rule and a vast body of secondary literature<sup>164</sup> say "no." The HIPAA statute, with respect to the enumerated public health activities listed in § 1320d-7(b), says "yes."<sup>165</sup>

As HHS drafted the Privacy Rule, the agency was keenly attentive to federalism concerns that favored a modest view of the regulation's preemptive impact. Executive Order 13132<sup>166</sup> on federalism became effective on November 4, 1999.<sup>167</sup> HHS's proposed Privacy Rule was issued the day before (on November 3) and thus did not follow that Executive Order. It did, however, comply<sup>168</sup> with the earlier, Reagan-era Executive Order 12612<sup>169</sup> on federalism. The final Privacy Rule issued in December 2000 embraced Executive Order 13132's requirements.<sup>170</sup> Empirical studies have found widespread disregard for Executive Orders 13132<sup>171</sup> and 12612<sup>172</sup> in many agencies'

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<sup>163</sup> See discussion *infra* this subpart.

<sup>164</sup> See discussion *supra* Part II.C.

<sup>165</sup> See discussion *supra* Part II.C.

<sup>166</sup> Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 4, 1999).

<sup>167</sup> *Id.* § 10(c).

<sup>168</sup> See Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 59,918, 60,048-49 (proposed Nov. 3, 1999) (to be codified at 45 C.F.R. pts. 160-64).

<sup>169</sup> Exec. Order No. 12,612, 52 Fed. Reg. 41,685 (Oct. 26, 1987).

<sup>170</sup> Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,797, 798 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160, 164).

<sup>171</sup> See CATHERINE M. SHARKEY, FEDERAL AGENCY PREEMPTION OF STATE LAW 63-64 (2011), available at [http://www.acus.gov/wp-content/uploads/downloads/2011/02/Sharkey-Final-ACUS-Report\\_12\\_20.pdf](http://www.acus.gov/wp-content/uploads/downloads/2011/02/Sharkey-Final-ACUS-Report_12_20.pdf).

<sup>172</sup> See *Implementation of Executive Order 12,612 in the Rulemaking Process: Hearing Before the S. Committee on Government Affairs*, 106 Cong. 1, 4 (May 5, 1999) (statement of L. Nye Stevens, Director, Federal Management and Workforce Issues,

rulemaking proceedings. The HIPAA Privacy Rule was not an example of this phenomenon. HHS followed the Executive Orders' procedures and held the required consultations with the states. These consultations revealed that states were very "concern[ed] that the final regulation would preempt all state privacy laws."<sup>173</sup> HHS reassured them that "the regulation" would not preempt more stringent state privacy laws, and the states "generally accepted our approach to the preemption issue."<sup>174</sup> What was perhaps left unsaid was that *the regulation* had no need to preempt more stringent state privacy laws, because the statute had already taken care of that unpleasant bit of business. Why rub salt into the states' wounds, when it is not actually necessary for the regulation to do so?

The HIPAA Privacy Rule had a famously contentious rulemaking history. The proposed regulation drew more than 52,000 public comments<sup>175</sup> and the final rule of December 2000 subsequently was reopened for a second round of comments<sup>176</sup> and amendments.<sup>177</sup> Consensus was hard to achieve and, in fact, was not fully achieved. The Privacy Rule continues to be disliked by all sides. For example, it is simultaneously criticized for allowing too much<sup>178</sup> and not enough<sup>179</sup> access to data and biospecimens. Modestly positioning the

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General Government Division) (finding only 5 of 11,414 rules issued between April 1996 and December 1998 to have included the federalism impact statement Exec. Order No. 12,612 required, and that only 27% of rules issued in this period cited Exec. Order No. 12,612).

<sup>173</sup> Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,797-82,798.

<sup>174</sup> *Id.* at 82,798.

<sup>175</sup> Ko, *supra* note 67, at 500; see also Standards for Electronic Transactions, 63 Fed. Reg. 25,272, 25,274 (proposed May 7, 1998) (to be codified at 45 C.F.R. pt. 142) (providing a brief summary of HIPAA's preemption provisions in the preamble to the proposed HIPAA Transactions Rule, which had been published shortly before work began on the Privacy Rule); Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 50,312 (noting ruefully, in the preamble to the final Transactions Rule, that that brief mention of preemption issues had drawn a number of comments even though HHS had not intended to address those issues in the Transactions Rule proceedings).

<sup>176</sup> Standards for Privacy of Individually Identifiable Health Information, 66 Fed. Reg. 12,738, 12,738 (Feb. 28, 2001).

<sup>177</sup> See Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53,182, 53,182 (Aug. 14, 2002) (amending various provisions of the 2000 final Privacy Rule but not making further changes to its preemption provisions).

<sup>178</sup> See, e.g., IOM, PRIVACY REPORT, *supra* note 20, at 66 (discussing surveys of public attitudes about nonconsensual access to data which the Privacy Rule allows in certain circumstances).

<sup>179</sup> See William Burman & Robert Daum, *Grinding to a Halt: The Effects of the*

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Privacy Rule as a floor of privacy protections may have had a calming effect during the fractious rulemaking process. By its own terms, the Privacy Rule is merely a floor, and that was all that needed to be discussed during the rulemaking. The Privacy Rule only becomes a ceiling in one narrow context — public health uses of data and biospecimens — and then only when read in conjunction with the HIPAA statute. The rulemaking carefully set the stronger statutory preemption provision at 42 U.S.C. § 1320d-7(b) to one side and avoided making it a topic of rulemaking discussions.

This explains the “missing tooth” in the Privacy Rule’s § 160.203: the regulation has blank space where the statute has a third prong of analysis. By remaining silent, the regulation leaves the third prong of preemption analysis to be performed through direct reference to the statute. In its rulemaking, HHS steered a careful course that avoided creating any record — either in the regulation or in its preambles — that might be seen as an agency interpretation that alters the meaning of 42 U.S.C. § 1320d-7(b). The agency was, in effect, preserving the third prong of statutory preemption analysis by ignoring it. The preambles’ curt statements about the statute’s public health “carve-out” acknowledge that 42 U.S.C. § 1320d-7(b) exists but do not delve into what it does. These same preambles offered thorough, high-quality analyses of many other topics. In contrast, their analysis of § 1320d-7(b) is strikingly vacuous and unpersuasive. It is as if the agency studiously censored this analysis to avoid making any statements that courts might later deem worthy of *Chevron* or *Skidmore* deference. The preambles do not interpret § 1320d-7(b) so much as they studiously avoid interpreting it, thus leaving the statute pristine for future interpretation by courts. As a result, nothing in the Privacy Rule or its preambles alters the fact that the statute preempts more stringent state privacy laws that interfere with the enumerated public health uses of data and biospecimens. The Privacy Rule’s preemption provisions are a masterpiece of regulatory modesty: they do only what the regulation must do and stay out of the way when Congress has done more.

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*Increasing Regulatory Burden on Research and Quality Improvement Efforts*, 49 *CLINICAL INFECTIOUS DISEASES* 328, 328 (2009) (arguing that “the application of the Health Insurance Portability and Accountability Act to research has overburdened institutional review boards (IRBs), confused prospective research participants, and slowed research and increased its cost”); Fred H. Cate, *Protecting Privacy in Health Research: The Limits of Individual Choice*, 98 *CALIF. L. REV.* 1765, 1797 (2010) (“Consent requirements [imposed by the HIPAA Privacy Rule] not only impede health research, but may actually undermine privacy interests.”).



An essential point the regulation did need to address is how the Privacy Rule itself interacts with state and federal public health laws. HHS noted that 42 U.S.C. § 1320d-7(b) “carves out” certain areas of state authority that are not “limited or invalidated by the provisions of Part C of title XI [of the Social Security Act, HIPAA’s Administrative Simplification Provisions]”.<sup>180</sup> This implies that the Privacy Rule must neither *preempt* nor *regulate* the enumerated public health activities. The saving clause at 45 C.F.R. § 160.203(c) takes care of this first point: it prevents the Privacy Rule from *preempting* state laws that provide for the enumerated public health activities. Elsewhere, HHS made sure that the Privacy Rule avoids *regulating* the enumerated public health activities. It did this by granting the enumerated public health activities an exception from having to comply with the Privacy Rule’s major substantive requirement of obtaining patient authorization for uses and disclosures of protected health information (data and biospecimens). This exception, which appears at 45 C.F.R. § 164.512(b), allows nonconsensual access to data and biospecimens for use in the enumerated public health activities. HHS included this exception in direct response to 42 U.S.C. § 1320d-7(b).<sup>181</sup> This exception applies to public health activities that are authorized “by law” (state and federal).<sup>182</sup> The activities in question include “public health surveillance, public health investigations, and public health interventions” as well as routine public health reporting and collection of vital statistics.<sup>183</sup> This corresponds to the range of public health activities that are protected by the statute’s rule of construction.<sup>184</sup>

These two provisions — the saving clause at § 160.203(c) and the exception at § 164.512(b) — are not broad interpretations but rather specific applications of the statute. They address a narrow question, “How does 42 U.S.C. § 1320d-7(b) limit the Privacy Rule itself?” This accomplishes some but not all of the work that the statutory rule of

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<sup>180</sup> See Standards for Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,480 (Dec. 28, 2002) (to be codified at 45 C.F.R. pts. 160 and 164) (discussing the impact of 42 U.S.C. § 1320d-7(b) in the preamble to the final Privacy Rule).

<sup>181</sup> See Standards for Individually Identifiable Health Information, 64 Fed. Reg. 59,918, 59,998-99 (Dec. 28, 2002) (indicating, in the preamble to the proposed Privacy Rule, that HHS was addressing concerns raised by 42 U.S.C. § 1320d-7(b) by allowing nonconsensual disclosures of protected health information for public health activities under the proposed 45 C.F.R. § 160.510(b), which subsequently was renumbered to § 160.512(b)).

<sup>182</sup> 45 C.F.R. § 164.512(b)(1) (2013).

<sup>183</sup> *Id.*

<sup>184</sup> 42 U.S.C. § 1320d-7(b) (2005).

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construction envisions.<sup>185</sup> The remaining work, such as preempting a more stringent state law that interferes with the enumerated public health activities, was left for the statute to do.

It is permissible for a regulation to limit its own scope, leaving some questions to be resolved by direct reference to its enabling statute. At its core, the choice to do so is a decision about who is better equipped to interpret a statute's express preemption provisions: (1) a regulator that in this case possessed immense subject-area legal knowledge but no particular expertise of preemption doctrine or of state privacy laws and their potential interactions with public health laws; or (2) the courts. The drafters of the HIPAA Privacy Rule declined to dabble in abstract administrative interpretation of the far reaches of HIPAA's statutory power to preempt state privacy law. This left the matter for courts to decide in the context of specific cases and controversies where state privacy laws have been saved by the Privacy Rule but allegedly are inflicting concrete injuries to the public's health. This may well have been the right place to leave it.

### C. *If This Is the Ceiling, Where Exactly Is It?*

The third prong of HIPAA preemption analysis has the potential to facilitate access to data for socially beneficial public health studies by fostering uniform national privacy standards. However, two important limitations must be recognized. First, this mechanism does not apply to interoperable health data networks generally.<sup>186</sup> It only applies to interoperable health data networks insofar as they are used in the enumerated public health activities. Non-uniform state privacy standards may continue to pose problems for interoperable health data networks directed at non-public-health purposes. Here, however, it is encouraging to note that Rosenbaum et al. found no evidence that more stringent state privacy laws actually interfere with access to data by healthcare providers for purposes of medical treatment, healthcare quality improvement, or production of transparent information about healthcare system performance.<sup>187</sup> Their research found that, with respect to these uses, the alleged barriers to interoperability posed by

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<sup>185</sup> See discussion *supra* Part III, introductory paragraphs (discussing the full range of issues that the statutory rule of construction addresses).

<sup>186</sup> See 42 U.S.C. § 1320d-7(b) (protecting public health activities but not protecting interoperable health data networks generally, thus implying that interoperable health data networks are protected only insofar as they are instrumental to one of the protected public health activities).

<sup>187</sup> Rosenbaum et al., *supra* note 15, at 1, 4.

unpreempted, more stringent state privacy laws are “more perceived than real.”<sup>188</sup>

A second limitation is that preemption helps only if the federal standards are better than the state laws they displace. Many people feel the Privacy Rule itself impedes access to data and biospecimens for research and public health studies.<sup>189</sup> If the Privacy Rule is to be the ceiling of privacy standards for the enumerated public health activities, where exactly is that ceiling and will it still impair public health access to data and biospecimens? The response to this second concern is that the Privacy Rule’s framework for public health access to data and biospecimens is more access-friendly than it is generally understood to be.

The Privacy Rule owes its bad reputation, in part, to unfortunate timing. Institutions began complying with the Privacy Rule in 2003-2004.<sup>190</sup> Within a few short years, there were complaints that “application of the Health Insurance Portability and Accountability Act to research has overburdened institutional review boards (IRBs), confused prospective research participants, and slowed research and increased its cost.”<sup>191</sup> IRBs are private ethical review bodies often staffed by employees of institutions that hold data and biospecimens or that wish to study them.<sup>192</sup> IRBs play a role in implementing various aspects of the Privacy Rule and the Common Rule,<sup>193</sup> a major federal research regulation that also imposes ethical and privacy requirements on research uses of data and specimens.<sup>194</sup>

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<sup>188</sup> *Id.*

<sup>189</sup> See IOM, PRIVACY REPORT, *supra* note 20, at 200-09 (reporting results of multiple surveys that found adverse impacts on studies that require access to data and biospecimens following implementation of the Privacy Rule); see also Burman & Daum, *supra* note 179, at 328; Cate, *supra* note 179, at 1797.

<sup>190</sup> 45 C.F.R. § 164.534 (2013).

<sup>191</sup> Burman & Daum, *supra* note 179, at 328.

<sup>192</sup> See 45 C.F.R. §§ 46.103(b), 46.107-108 (describing IRBs for purposes of the Common Rule); *id.* § 164.512(i)(2)(iv) (allowing waivers of consent for research under the HIPAA Privacy Rule to be approved by either a Common Rule-compliant IRB or by a HIPAA-compliant “privacy board” that is similar to an IRB).

<sup>193</sup> Federal Policy for the Protection of Human Subjects (Common Rule), 45 C.F.R. §§ 46.101-46.124.

<sup>194</sup> See 45 C.F.R. § 46.102(f) (2012) (defining “human subject” to include living individuals about whom an investigator obtains identifiable private information); *Guidance on Research Involving Coded Private Information or Biological Specimens* U.S. DEP’T OF HEALTH & HUMAN SERVS. (Oct. 8, 2008) <http://www.hhs.gov/ohrp/policy/cdebiol.html> [hereinafter *OHRP Guidance*] (interpreting how the Common Rule applies to research with data and biospecimens and describing circumstances in which such research will be subject to the Common Rule’s informed consent requirements).

After HIPAA, IRBs did seem to become bogged down in data- and biospecimen-related workload, but savvy biomedical investigators should have been the first to point out that the proximity of two events in time does not always imply a causal relationship. The HIPAA Privacy Rule took blame for *causing* the sudden uptick in IRB workload, but sheer coincidence cannot be ruled out.<sup>195</sup> The first decade of this century saw a flowering of informational research and an epochal shift in the relative mix of informational and clinical research activities.<sup>196</sup> This increase in the volume of informational research naturally implied a need for IRBs to devote more of their time to questions of privacy and access to data and biospecimens. To blame the Privacy Rule for this trend is methodologically flawed.

Confusion about how the Privacy Rule works has compounded its bad reputation.<sup>197</sup> The Privacy Rule has a number of similarities to the Common Rule, an older regulation that many research institutions had been implementing for decades when the Privacy Rule went into effect. Both regulations impose consensual ordering as their baseline rule: they require that the patient sign a privacy authorization<sup>198</sup> or informed consent<sup>199</sup> (or both) before another party can gain access to the patient's health data or biospecimens. Both regulations shift to a regime of nonconsensual access in various situations.<sup>200</sup> Both allow nonconsensual access to data and specimens for use in public health activities. There, the similarity ends. The two regulations allow public health access to data and specimens through very different mechanisms.

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<sup>195</sup> See Burman & Daum, *supra* note 179, at 328; see also IOM, PRIVACY REPORT, *supra* note 20, at 201 (noting that the Privacy Rule has “increased the costs of conducting research by requiring more paperwork and complicating the IRB approval process”).

<sup>196</sup> See *supra* notes 29-34 and accompanying text.

<sup>197</sup> See IOM, PRIVACY REPORT, *supra* note 20, at 9-10 (noting that the Privacy Rule's regulatory language “often is not easily understandable” and recommending that HHS should develop guidance materials to help IRBs understand and apply the Privacy Rule more consistently and effectively).

<sup>198</sup> See 45 C.F.R. § 164.508 (2013) (describing authorization requirements of the HIPAA Privacy Rule).

<sup>199</sup> See 45 C.F.R. § 46.116 (describing informed consent requirements of the Common Rule).

<sup>200</sup> See 45 C.F.R. § 164.512 (describing exceptions to the HIPAA Privacy Rule's authorization requirements); see also *id.* at §§ 46.101(b)-(d) (describing exemptions to the Common Rule); *id.* at §§ 46.102(d), (f) (defining the terms “research” and “human subject”); OHRP Guidance, *supra* note 194 (determining that research involving only coded private information and biospecimens does not fall within the definition of human subject research that requires informed consent).

The Common Rule, as applied at many institutions, gives IRBs a central role in determining whether data or biospecimens can be released without consent for use in public health studies. The Common Rule defines research as a “systematic investigation . . . designed to develop or contribute to generalizable knowledge” and subjects research to IRB review and informed consent requirements if the research involves human subjects.<sup>201</sup> In contrast, the Common Rule does not define public health activities or explicitly exempt them from the Common Rule’s requirements.<sup>202</sup> To decide whether the Common Rule applies to a particular study, institutions must assess whether the activity is public health “practice” (which does not require IRB review and informed consent under the Common Rule) or “research” (which requires both).<sup>203</sup>

The Common Rule does not require institutions to involve their IRBs in making this assessment.<sup>204</sup> In practice, many institutions do turn to their IRBs to help them assess whether specific activities fall under the Common Rule.<sup>205</sup> There are various analytical frameworks for determining whether an activity is public health practice or research.<sup>206</sup> These frameworks weigh a number of factors, often with

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<sup>201</sup> 45 C.F.R. § 46.101(a); *id.* § 46.102(d).

<sup>202</sup> Evans, *Much Ado*, *supra* note 39, at 114.

<sup>203</sup> HODGE & GOSTIN, *supra* note 117, at 7, 14-17.

<sup>204</sup> *See id.*

<sup>205</sup> *See, e.g., Exempt Research Determination-FAQs*, U.S. DEPT. OF HEALTH & HUMAN SERVS., <http://answers.hhs.gov/ohrp/categories/1564> (last visited Dec. 28, 2012) (discussing the closely related problem of assessing whether a specific research activity fits within one of the Common Rule’s exemptions, and recommending that researchers should not be left to assess this matter themselves because of their potential conflict of interest); *see also Must There be Review by Someone Other Than the Investigator Before a Research Study is Determined to be Exempt?*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, <http://answers.hhs.gov/ohrp/questions/7292> (last visited Dec. 28, 2012) (noting that the regulations do require institutions to make accurate determinations about whether the regulations apply and that “[t]he person(s) authorized to make this determination should have access to sufficient information to make a correct determination”). In practice, IRB’s familiarity with the regulation and their perceived independence make them favored candidates to make these determinations.

<sup>206</sup> *See, e.g.,* Ctrs. for Disease Control & Prevention & U.S. Dep’t of Health & Human Servs., *HIPAA Privacy Rule and Public Health*, in 52 MORBIDITY & MORTALITY WKLY. REP. 1, 10 (2003), *available at* <http://www.cdc.gov/mmwr/pdf/other/m2e411.pdf> (discussing the distinction between public health practice and public health research and identifying factors to consider when making this determination); CENTERS FOR DISEASE CONTROL & PREVENTION, *GUIDELINES FOR DEFINING PUBLIC HEALTH RESEARCH AND NON-RESEARCH 2* (1999), *available at* <http://www.cdc.gov/od/science/integrity/docs/defining-public-health-research-non-research-1999.pdf> (same); HODGE & GOSTIN, *supra* note 117, at 7-9, 47-55 (same); Paul J. Amoroso & John P. Middaugh,

an emphasis on whether the activity will produce generalizable results. Generalizability features prominently in the Common Rule's definition of research,<sup>207</sup> so if a study produces generalizable results, this tends to suggest that it may be "research" that requires informed consent (or a waiver of consent).<sup>208</sup> However, there are other factors to consider, and some of these require subjective judgments.<sup>209</sup> Because institutions often involve their IRBs in these assessments, public health access under the Common Rule may turn on discretionary judgments by IRBs.<sup>210</sup>

In contrast, the Privacy Rule calls for no IRB involvement in decisions to disclose data and biospecimens for use in public health studies.<sup>211</sup> The relevant provision of the Privacy Rule is 45 C.F.R. § 164.512(b)(1)(i). This is part of the public health exception HHS added to the Privacy Rule as a response to the statutory rule of construction at 42 U.S.C. § 1320d-7(b).<sup>212</sup> As discussed earlier, § 1320d-7(b) implies that the Privacy Rule must not impose substantive regulatory requirements that limit the enumerated public health activities. HHS complied with this directive in two ways: (1) HHS granted the enumerated public health activities a broad exception

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Commentary, *Research vs. Public Health Practice: When Does a Study Require IRB Review?*, 36 PREVENTIVE MED. 250, 250-53 (2003) (same); James G. Hodge, Jr., *An Enhanced Approach to Distinguishing Public Health Practice and Human Subjects Research*, 33 J.L. MED. & ETHICS 125, 127-29 (2005) (same); Dixie E. Snider, Jr. & Donna F. Stroup, *Defining Research When It Comes to Public Health*, 112 PUB. HEALTH REPS. 29, 30 (1997) (same); *OPRR Guidance on 45 C.F.R. § 46.101(b)(5): Exemption for Research and Demonstration Projects on Public Benefit and Service Programs*, U.S. DEP'T OF HEALTH & HUMAN SERVS., <http://www.hhs.gov/ohrp/policy/exmpt-pb.html> (last visited Nov. 14, 2008) (same).

<sup>207</sup> 45 C.F.R. § 46.102(d) (2009).

<sup>208</sup> HODGE & GOSTIN, *supra* note 117, at 54 (noting that if an activity does not "[generate] knowledge that will benefit those beyond the community of persons who bear the risks of participation," it "is likely practice," but recommending additional analysis if the activity will produce knowledge that is generalizable to other populations); Evans, *Much Ado*, *supra* note 39, at 115-16 (noting that generalizability is not dispositive in determining that an activity is research, but it weighs in favor of such a finding).

<sup>209</sup> See HODGE & GOSTIN, *supra* note 117, at 7-9, 47-55 (proposing a framework that considers a wide range of factors including determinations about the likely beneficiaries of the study and about the investigator's primary intentions in pursuing the research).

<sup>210</sup> See Evans, *Much Ado*, *supra* note 39, at 117-18 (providing an example of the discretionary power IRBs can exercise to block congressionally authorized public health uses of data, even when OHRP has made a determination that the use is for public health practice).

<sup>211</sup> See 45 C.F.R. § 164.512(b)(1)(i) (2009) (failing to specify a role for IRBs).

<sup>212</sup> See discussion *supra* notes 180-181 and accompanying text.

from the Privacy Rule's usual authorization requirements; and (2) HHS did not subject disclosures of data and specimens under this exception to IRB review.<sup>213</sup>

How, then, does the Privacy Rule's public health exception work? Entities that hold data or tissue resources do not need to obtain individual authorizations before sharing these resources with a "public health authority that is authorized by law to collect or receive such information."<sup>214</sup> For this purpose, public health authorities include governmental agencies as well as entities acting under a contract with an agency.<sup>215</sup> Thus, a private-sector research institution conducting legally authorized public health studies under contract with a governmental public health agency could receive data and tissue resources under this exception. This exception allows disclosure of data and biospecimens for various purposes, specifically including public health surveillance and investigations.<sup>216</sup> The Privacy Rule draws no distinction between investigations that produce generalizable knowledge and those that do not. This clearly seems to allow disclosures to public health authorities for use in research as well as in traditional public health practice activities: the Privacy Rule, like the Common Rule, defines research as "systematic investigation[s] . . . [that] contribute to generalizable knowledge."<sup>217</sup> The HHS Office for Civil Rights, which administers the Privacy Rule, has never interpreted this regulation otherwise, but it is probably fair to say that there is some uncertainty about this point.

Fortunately, the Privacy Rule is unambiguous on several other points, and these clarify how the public health exception functions. A data-holder (or tissue repository) that is disclosing data or biospecimens to a public health authority under this exception *does not* need to conduct an IRB review and *does not* need to make inquiries into the nature of the intended data use.<sup>218</sup> Instead, the data-holder or tissue repository only needs to verify three things before making the disclosure: (1) that the person that will receive the data or specimens

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<sup>213</sup> See 45 C.F.R. § 164.512(b).

<sup>214</sup> *Id.* § 164.512(b)(1)(i).

<sup>215</sup> *Id.* § 164.501 (2009).

<sup>216</sup> *Id.* § 164.512(b)(1)(i).

<sup>217</sup> *Id.* § 164.501.

<sup>218</sup> See *id.* § 164.512(b)(1); see also KRISTEN ROSATI, BARBARA EVANS & DEVEN MCGRAW, HIPAA AND COMMON RULE COMPLIANCE IN THE MINI-SENTINEL PILOT 7 (2010), available at [http://mini-sentinel.org/work\\_products/About\\_Us/HIPAA\\_and\\_CommonRuleCompliance\\_in\\_the\\_Mini-SentinelPilot.pdf](http://mini-sentinel.org/work_products/About_Us/HIPAA_and_CommonRuleCompliance_in_the_Mini-SentinelPilot.pdf) (discussing the lack of IRB requirements in § 164.512(b)(1)).

really is a public health official;<sup>219</sup> (2) that the recipient has legal authority to request the data or specimens;<sup>220</sup> and (3) that the requested items are the minimum necessary to fulfill the public health purpose.<sup>221</sup> This three-step verification process is set out in the “verification standards” at § 164.514 of the Privacy Rule.<sup>222</sup> A data holder or tissue bank, when making these disclosures, is entitled to rely on the public health authority’s representations that the request is legally authorized and meets the minimum necessary condition.<sup>223</sup> In other words, the entity making the disclosure can take the public health authority’s word for it and will not face any penalties if the public health authority happens to be mistaken and does not, in fact, have legal authority to make the request or has requested more than the minimum that actually was necessary to do its work.<sup>224</sup>

The Privacy Rule thus encourages institutions that hold data and biospecimens to defer to public health authorities’ interpretations of the laws they administer. Here again, the Privacy Rule was making an assessment of institutional competence. The individual’s interest in medical privacy sometimes must give way to broader public interests in public welfare, safety, and health. Deciding when this should occur is one of the major challenges of privacy law. Legal rules cannot enunciate a balance that will be appropriate in every circumstance; the right balance is so fact-dependent that it is impossible to describe it ahead of time. Instead, law can only speak to the process through

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<sup>219</sup> See 45 C.F.R. § 164.514(h)(2)(ii) (allowing disclosure to officials including agency employees and persons who can prove they have a contract or other authorization to act on the government’s behalf).

<sup>220</sup> See 45 C.F.R. § 164.514(h)(2)(iii) (allowing the covered entity to rely on the written statement of a public agency concerning the legal authority under which it is requesting protected health information, or an oral statement if a written statement is impracticable); Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,547 (Dec. 28, 2000) (explaining in the Preamble to the Privacy Rule that the verification process can rely on “reasonable” documentation).

<sup>221</sup> 45 C.F.R. § 164.514(d)(3)(iii). While § 13405(b) of the HITECH Act, codified at 42 U.S.C.A. § 17935 (West 2010 & Supp. 2011), contains a provision requiring covered entities to determine what is the minimum amount of protected health information for a disclosure, recently proposed amendments to the HIPAA Privacy Rule to implement the HITECH Act did not modify a covered entity’s ability to rely on minimum necessary representations by public officials. See Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act, 78 Fed. Reg. 5566, 5700 (Jan. 25, 2013) (to be codified at 45 C.F.R. pts. 160, 164) (revising various parts of 45 C.F.R. § 164.514, but not altering § 164.514(d)(3)(iii)).

<sup>222</sup> 45 C.F.R. §§ 164.514(d)(3)(iii), (h)(2)(ii), (h)(2)(iii).

<sup>223</sup> See *supra* notes 209-12.

<sup>224</sup> See *id.*



which these balances should be struck. This includes designating a decision-maker to strike the balance. Who should that be: individuals, regulators (including the IRBs to which they delegate day-to-day decisions), or legislative bodies and the public health authorities that administer the laws they pass?

The Privacy Rule reflects a radically different view of institutional competence than the Common Rule does. Both regulations take decisions about public health matters out of the hands of individuals by allowing nonconsensual access to data and biospecimens for use in public health activities. The people are, after all, the “least accountable branch,”<sup>225</sup> subject to the fewest checks and balances in our constitutional order.<sup>226</sup> As individuals faced with a request to use their data or specimens for public health purposes, their conflicts of interest may disqualify them from striking a public-regarding balance of the competing interests. Some people consistently refuse to allow their data to be studied, even when a study might save or improve other people’s lives.<sup>227</sup> There are people in the world who are prepared to guard their medical secrets even at the cost of other people’s lives. The Common Rule and the Privacy Rule deny individuals the opportunity to make that choice.

Because the Common Rule does not define or exempt public health uses of data, it leaves important decisions (such as whether a specific use of data use requires informed consent) to be made by IRBs. Although IRBs are private bodies, they are established under the Common Rule and derive their decision-making authority from that regulation.<sup>228</sup> The regulatory agency that imbues IRBs with their

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<sup>225</sup> See generally Marci A. Hamilton, *The People: The Least Accountable Branch*, 4 U. CHI. L. SCH. ROUNDTABLE 1 (1996-1997) (using this phrase in connection with direct democracy rather than individual consensual ordering).

<sup>226</sup> *Id.* at 6.

<sup>227</sup> See, e.g., IOM, *PRIVACY REPORT*, *supra* note 20, at 84 (reporting results of a survey in which 8% of respondents had declined requests to use their data in research, with many citing purely personal reasons such as privacy concerns, lack of trust in researchers, concerns that the research would help people other than their own families, and concerns that participating in research would be unpleasant).

<sup>228</sup> See HODGE & GOSTIN, *supra* note 117, at 17 (noting that the “Common Rule vests authority within IRBs to approve, disapprove, or require modifications of all federally-funded human subjects research”); see also *Must There be Review by Someone Other Than the Investigator Before a Research Study is Determined to be Exempt?*, *supra* note 205 (noting that the Common Rule requires institutions to make accurate determinations about whether the regulation does or does not apply to their activities, which has the effect of causing IRBs to become involved in making jurisdictional determinations about whether the Common Rule’s requirements apply to specific activities).

decision-making power remains responsible for setting standards and providing guidance to aid those decisions. As a result, IRBs' competence to balance privacy and competing values is only as good as the regulator's competence to do so. In practice, it may be considerably worse, since IRBs have many imperfections as guardians of the public's interests. IRBs are private, unelected, and potentially conflicted<sup>229</sup> bodies unbound by even the most basic set of public-regarding<sup>230</sup> norms.<sup>231</sup> Their exclusive mandate to protect human research subjects leaves IRBs potentially susceptible to the "single-value" decision-maker problem: a risk of excessive zeal in pursuit of that one single value to the detriment of all competing interests.<sup>232</sup> Moreover, "a large number" of comments on HHS's original HIPAA Privacy Rule proposal expressed doubt about IRBs' ability to balance public and private interests.<sup>233</sup>

These comments came in response to a different section of the Privacy Rule: its waiver provisions that allow IRBs to approve nonconsensual access to data and biospecimens for use in research.<sup>234</sup>

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<sup>229</sup> See Barbara J. Evans, *Ethical and Privacy Issues in Pharmacogenomic Research*, in PHARMACOGENOMICS: APPLICATIONS TO PATIENT CARE 313, 332 (Howard L. MacLeod et al. eds., 2d ed. 2009).

<sup>230</sup> See Jody Freeman, *Extending Public Law Norms Through Privatization*, 116 HARV. L. REV. 1285, 1351 (2003) (discussing the importance of public norms of accountability, due process, equality, and rationality when private actors perform services or deliver goods traditionally provided by the state); Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U. L. REV. 543, 574-75 (2000) (expressing concern that private actors may be less attentive than governmental actors are to public-regarding norms and suggesting, as possible solutions, to impose procedural controls on private actors or to infuse private law with "public law norms requiring fair and rational decision making"); Martha Minow, *Public and Private Partnerships: Accounting for the New Religion*, 116 HARV. L. REV. 1229, 1266-69 (2003) (discussing the need for a "public framework of accountability when governments privatize functions or activities that have been public").

<sup>231</sup> See Carl H. Coleman, *Rationalizing Risk Assessment in Human Subject Research*, 46 ARIZ. L. REV. 1, 13-17 (2004) (describing the procedural inadequacies of IRB review under the Common Rule); Barbara J. Evans, *Congress' New Infrastructural Model of Medical Privacy*, 84 NOTRE DAME L. REV. 585, 634-35 (2009) (noting the Common Rule's failure to require reasoned, evidence-based IRB decision-making; independence of IRB members; notice or other basic due process rights for parties affected by IRB decisions; or reviewable records and rights to appeal IRB decisions).

<sup>232</sup> James V. DeLong, *Informal Rulemaking and the Integration of Law and Policy*, 65 VA. L. REV. 257, 278-79 (1979) (describing the risk of non-neutral decision-making and over-zealotry by regulatory decisionmakers that have a mandate to pursue a single value — such as consumer safety or clean air).

<sup>233</sup> Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,698 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160, 164).

<sup>234</sup> 45 C.F.R. § 164.512(b)(1)(i) (2009).

HHS's original proposal would have required IRBs to determine, before approving a waiver, that "the research is of sufficient importance so as to outweigh the intrusion of the privacy of the individual whose information is subject to the disclosure."<sup>235</sup> This proposal drew many adverse comments<sup>236</sup> that warned, for example, that this criterion was subjective and would be inconsistently applied by IRBs and that it relied on conflicting value judgments as to whether research is important.<sup>237</sup> Indeed, balancing privacy and competing values does involve conflicting value judgments — weighing them is the essence of the exercise. HHS ultimately dropped the troublesome balancing requirement from the list of determinations that an IRB must make when approving nonconsensual research access to data and biospecimens.<sup>238</sup>

The fact that IRBs had professed incompetence to balance public and private interests in the research context may have been on HHS's mind as it addressed the role of IRBs in the public health context. The Privacy Rule grants IRBs no role in approving disclosures of data for the enumerated public health purposes. It recognizes state legislatures and "Congress, the most accountable branch," as the appropriate bodies to decide whether specific public health uses of data and biospecimens warrant intrusions on individual privacy.<sup>239</sup> When a legislative body has authorized a public health use of data or biospecimens, the Privacy Rule treats this as a broad consent of the people to the study. The Privacy Rule defers to decisions by duly-elected legislatures (state and federal), as interpreted by public health authorities charged with implementing public health statutes.

The Privacy Rule's public health exception<sup>240</sup> is widely — and sometimes wildly — misunderstood. Even the Institute of Medicine's 2009 report on the HIPAA Privacy Rule exhibited the general muddlement: The IOM's report never discussed the § 164.514 verification standards, which are key provisions through which HIPAA

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<sup>235</sup> Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,698.

<sup>236</sup> *Id.*

<sup>237</sup> *Id.*

<sup>238</sup> *See id.* (revising the balancing requirement in the December 2000 version of the Privacy Rule); Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53,182, 53,270 (Aug. 14, 2002) (dropping the balancing requirement altogether in the currently effective version of HIPAA's waiver provisions at 45 C.F.R. § 164.512(b)(i)).

<sup>239</sup> Eskridge & Baer, *supra* note 7, at 1086-87 (citing *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.* 467 U.S. 837, 865-66 (1984)).

<sup>240</sup> 45 C.F.R. § 164.512(b)(1)(i) (2009).

facilitates public health access to data. Instead, it offered a lengthy discussion of the distinction between public health practice and public health research<sup>241</sup> and seemed to imply that IRBs need to analyze this distinction when applying the HIPAA Privacy Rule.<sup>242</sup> The Privacy Rule certainly does not require this; it differs from the Common Rule in this respect. As just explained, the Privacy Rule does not involve IRBs in decisions to disclose data to public health authorities. Institutions that hold data and biospecimens merely need to comply with the three-step verification process, which is highly deferential to legislatures and the public health authorities that implement their statutes.<sup>243</sup>

Confusion about the Privacy Rule continues to thwart access to data for the enumerated public health activities. In one recent congressionally authorized public health study,<sup>244</sup> almost 5% of IRBs blocked access to data.<sup>245</sup> They had no authority to do so under the Common Rule. The HHS Office for Human Research Protections (OHRP), which implements the Common Rule, had determined that the study was a public health activity not subject to that regulation.<sup>246</sup> They had no authority to do this under the Privacy Rule. It envisions no role for IRBs in approving disclosures of data to a public health authority, which, in this case, had supplied all the documentation that the Privacy Rule's verification standards require.<sup>247</sup> In effect, private IRBs were nullifying a congressional determination that a public health investigation was necessary. The phenomenon of IRB nullification appears to be unmoored from any legal basis. It is

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<sup>241</sup> IOM, *PRIVACY REPORT*, *supra* note 20, at 133-36.

<sup>242</sup> *Id.* at 131, 133.

<sup>243</sup> 45 C.F.R. §§ 164.514(d)(3)(iii), (h)(2)(ii), (h)(2)(iii).

<sup>244</sup> Sarah L. Cutrona et al., *Design for Validation of Acute Myocardial Infarction Cases in Mini-Sentinel*, 21 *PHARMACOEPIDEMOLOGY & DRUG SAFETY* 274, 274-281 (2012).

<sup>245</sup> *Id.* at 278-79 (reporting that only 143 of 153 requested medical charts were provided, with seven of the ten missing charts withheld because of IRB concerns that patient consent was required).

<sup>246</sup> See Letter from Jerry Menikoff, Dir., Office for Human Res. Prot., to Rachel E. Behrman, Acting Assoc. Dir. of Med. Pol'y, Ctr. for Drug Evaluation and Research, U.S. Food & Drug Admin. (Jan. 19, 2010), reproduced in ROSATI ET AL., *supra* note 218, at 10, available at [http://mini-sentinel.org/work\\_products/About\\_Us/HIPAA\\_and\\_CommonRuleCompliance\\_in\\_the\\_Mini-SentinelPilot.pdf](http://mini-sentinel.org/work_products/About_Us/HIPAA_and_CommonRuleCompliance_in_the_Mini-SentinelPilot.pdf) (deeming Sentinel activities not to be regulated by the Common Rule); see also Letter from Rachel Behrman, Sentinel Initiative Exec. Sponsor, to Dr. Richard Platt, Harvard Med. Sch. & Harvard Pilgrim Health Care (July 19, 2010), reproduced in ROSATI ET AL., *supra* note 218, at 12-14 (emphasizing that all presently planned uses of the Mini-Sentinel System constitute public health activities by the FDA).

<sup>247</sup> Cutrona et al., *supra* note 244, at 278.

possible that the IRBs believed they were implementing more stringent standards of state privacy law. If so, however, they were mistaken. Section 1320d-7(b) of the HIPAA statute preempts such laws if they interfere with enumerated public health activities as, in this example, the IRBs clearly did. Decisions by IRBs to refuse access to data and specimens for enumerated public health activities need to be seen as what they are; these decisions are not grounded in law and rather are grounded in the natural human reluctance to share.

The HIPAA Privacy Rule appropriately removes IRBs from decisions about public health access to data. It defers to federal and state legislative bodies and public health authorities that interpret and implement the statutes they pass.<sup>248</sup> This is, above all, a choice about institutional competence. The Privacy Rule treats legislatures as the most competent institutions to balance the diverse interests implicated by public health access to private information. Individuals, regulatory agencies, and private, unaccountable IRBs play no role in its balancing process.

#### CONCLUSION

Reading statutes has a salutary effect in an age of well-settled rumor. The HIPAA statute — if only people would read it — is more preemptive than it is widely understood to be. This conclusion swims against a torrent of opinion from seemingly authoritative sources. For example, the FDA has stated, in connection with its Sentinel Initiative,<sup>249</sup> that “Federal regulations, including the HIPAA Privacy Rule constitutes a minimum for privacy protection, so states may enact more rigorous privacy protection if desired.”<sup>250</sup> While this statement would be correct in many contexts, it is false in the context of FDA’s Sentinel Initiative, which is a multi-state public health data network authorized by federal statute.<sup>251</sup> It harnesses insurance and

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<sup>248</sup> See *supra* notes 215-223 and accompanying text.

<sup>249</sup> Rachel E. Behrman et al., *Developing the Sentinel System — A National Resource for Evidence Development*, 364 NEW ENG. J. MED. 498, 498 (2011); see also U.S. FOOD & DRUG ADMIN., THE SENTINEL INITIATIVE: NATIONAL STRATEGY FOR MONITORING MEDICAL PRODUCT SAFETY 13-17 (2008), available at <http://www.fda.gov/downloads/Safety/FDAsSentinelInitiative/UCM124701.pdf> (describing the Sentinel Initiative); *FDA’s Sentinel Initiative*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Safety/FDAsSentinelInitiative/default.htm> (last updated Oct. 5, 2011) (discussing recent progress in implementing the Sentinel Initiative).

<sup>250</sup> *FDA’s Sentinel Initiative - Deliverables from Completed Contracts*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Safety/FDAsSentinelInitiative/ucm149343.htm> (last updated Jan. 20, 2012).

<sup>251</sup> See 21 U.S.C. § 355(k)(3) (2012) (authorizing FDA to develop a postmarket

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clinical data for use in drug safety surveillance and investigations<sup>252</sup> and has been deemed to be a public health activity.<sup>253</sup> Quite clearly, the Sentinel Initiative is one of the enumerated public health activities for which the HIPAA Privacy Rule sets both a ceiling and a floor on privacy protections. States may enact more rigorous privacy protections if they desire, *but those state protections are preempted* to the extent that they interfere with projects like the Sentinel Initiative.

The rule of construction at 42 U.S.C. § 1320d-7(b) is a forgotten statute. This Article is offered as a simple reminder that it is there and it is unambiguous. Moreover, it is profoundly important in an era when lives literally depend on public health access to data and biospecimens. This Article has only touched the surface of its many implications. As noted earlier, 90% of ERISA preemption scholarship was penned after that statute's sixteenth anniversary. As HIPAA passed its sixteenth birthday on August 21, 2012, there is a pressing need for a wider scholarly dialogue about its forgotten preemption provision.

There are unstudied mechanical questions of how to challenge a denial of access to data and biospecimens when access is protected under 42 U.S.C. § 1320d-7(b). The Privacy Rule has no private right of action for the individuals whose privacy it purports to protect.<sup>254</sup> However, Rosenbaum et al. found a robust body of cases in which courts entertained challenges by parties denied access to data and by parties who wished to disclose (or not to disclose) data protected under the Privacy Rule. These cases arose in contexts other than public health activities but may offer useful insights on basic questions — such as standing and ripeness — that will arise in future cases to challenge more stringent state laws that interfere with public health access to data. The court's role in such cases will be to conduct a straightforward, fact-based inquiry to assess whether, in the

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risk identification and analysis system for use in overseeing the safety of approved drugs).

<sup>252</sup> See Richard Platt et al., *The U.S. Food and Drug Administration's Mini-Sentinel Program: Status and Direction*, 21 PHARMACOEPIDEMIOLOGY AND DRUG SAFETY 1, 3 (2012) (discussing the Sentinel Initiative's pilot project, Mini-Sentinel); see also Lesley Curtis et al., *Design Considerations, Architecture, and Use of the Mini-Sentinel Distributed Data System*, 21 PHARMACOEPIDEMIOLOGY AND DRUG SAFETY 23, 26, 28 (2012) (discussing the types of data included in the system); Melissa Robb et al., *The U.S. Food and Drug Administration's Sentinel Initiative: Expanding the Horizons of Medical Product Safety*, 21 PHARMACOEPIDEMIOLOGY AND DRUG SAFETY 9, 9-10 (2012) (discussing various uses of the system).

<sup>253</sup> See Letter from Jerry Menikoff to Rachel E. Behrman, *supra* note 246, at 10.

<sup>254</sup> See 45 C.F.R. § 160.306 (2011); see also *Acara v. Banks*, 470 F.3d 569, 571-72 (5th Cir. 2006) (holding, in the first federal appellate decision to address this issue, that the Privacy Rule does not create a private right of action).

circumstances of the case, a contested state privacy law is “invalidat[ing] or limit[ing] the authority, power, or procedures established under any law providing for” the enumerated public health activities.<sup>255</sup> If so, the state law would be preempted by the HIPAA statute. For example, such “limiting” could occur if an institution that held data or biospecimens faced a state privacy tort claim for disclosing data or tissues for use in one of the enumerated public health activities, or if data-holding institutions refused to supply data to a public health authority because they feared liability under a state privacy statute. The HIPAA statute would preempt state law — apparently including common law tort actions — in these situations.<sup>256</sup>

Another promising area for future scholarship concerns the policy implications of 42 U.S.C. § 1320d-7(b). An obvious question is whether the enumerated public health activities are subject to adequate privacy and data security standards, commensurate with the privileged access to data that the HIPAA statute grants them. Also, there are ongoing questions about the adequacy of access to data and biospecimens for socially beneficial activities that do not qualify as enumerated public health activities: for example, socially beneficial research that happens not to be performed by a public health authority as defined in the HIPAA Privacy Rule. These questions continue to demand attention.

However, concerns about public health access to data and biospecimens often reflect misunderstandings of the law rather than genuine substantive failures of the law itself. Clearly, reform proposals that ask Congress to make HIPAA more preemptive are misguided to the extent that Congress already has done so. Congress is generally unwilling to amend its statutes to include provisions that already are there. The existing list of enumerated public health activities may well reflect the full range of purposes for which Congress is willing to preempt state privacy laws that protect individual privacy more stringently than the federal government does.

Similarly, it appears fruitless to press the agency to clarify the Privacy Rule’s preemptive impact when the agency, very clearly, has deferred to other institutions of government to interpret the full scope of HIPAA’s preemptive power. The toughest preemption questions are those that involve the preemption of state laws that are more stringent

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<sup>255</sup> 42 U.S.C. § 1320d-7(b) (2012).

<sup>256</sup> See 45 C.F.R. § 160.202 (2009) (interpreting “State law,” as used in the HIPAA Privacy Rule, to include “a constitution, statute, regulation, rule, common law, or other State action having the force and effect of law”).

than the HIPAA Privacy Rule. The agency has referred these questions to courts, where — based on the agency’s assessment of institutional competence — they belong. As for the more routine preemption questions, the agency responded to 42 U.S.C. § 1320d-7(b) by developing the Privacy Rule’s public health exception.<sup>257</sup> This exception simply defers to legislatures and public health authorities on routine questions such as whether a particular public health use of data is sufficiently important to warrant nonconsensual access to data and biospecimens. The agency has ceded a great deal of power to address preemption issues to other institutions of government, and those wishing to preempt state privacy laws in furtherance of socially beneficial public-health purposes need, henceforward, to work with those other institutions.

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<sup>257</sup> 45 C.F.R. § 164.512(b)(1)(i) (2013).