



MEMORANDUM

January 7, 2015

To: House Committee on Energy and Commerce
[REDACTED]

From: Andrew L. Nolan, Legislative Attorney, 7-0602
C. Stephen Redhead, Specialist in Health Policy, 7-2261

Subject: **Scope of the Legal Authority for the Office of the National Coordinator for Health Information Technology**

Pursuant to your request, this memorandum analyzes the scope of the current legal authority for the Office of the National Coordinator for Health Information Technology (ONC) within the Department of Health and Human Service (HHS). Specifically, this memorandum examines whether the ONC currently possesses the authority to create a Health IT Safety Center¹ (“Health IT Safety Center” or “Safety Center”) as referenced in an April 2014 report entitled “FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework” (“April 2014 Report”) jointly issued by the Food and Drug Administration (FDA), the Federal Communications Commission (FCC), and the ONC.² This memorandum begins by describing the history of ONC, the office’s legal authority with respect to the use and exchange of electronic health information within the United States, and the proposed Health IT Safety Center. The memorandum concludes by analyzing whether the agency is authorized to create the Safety Center as described in the April 2014 Report and elsewhere.

ONC and its Current Legal Authority

ONC was formally³ established in section 13101 of the Health Information Technology for Economic and Clinical Health (HITECH) Act within the American Recovery and Reinvestment Act of 2009 (ARRA).⁴ The purpose of the agency generally is to promote “the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information”⁵ The

¹ This memorandum does not examine whether ONC possesses the authority to take exploratory action respecting the Health IT Safety Center, such as entering into contracts or issuing grants developing the concept of the Safety Center.

² See FDA, FCC & ONC, “FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework,” April 2014, available at http://www.healthit.gov/sites/default/files/fdasiahealthitreport_final.pdf (herein “FDASIA Report”).

³ ONC was originally created by Executive Order 13335 on April 27, 2004, an order naming ONC as the “primary advisor” for HHS for health information technology. See Exec. Order No. 13335, 69 FED REG. 24059, 59 (April 30, 2004) (“The Secretary of Health and Human Services (Secretary) shall establish within the Office of the Secretary the position of National Health Information Technology Coordinator.”).

⁴ See Pub. L. 111-5, 123 Stat. 115, 230, codified at 42 U.S.C. § 300jj-11(a).

⁵ See 42 U.S.C. § 300jj-11(b). The HITECH Act specifies several more broad-based concerns and purposes for ONC, including promoting the security of each patient’s health information, see 42 U.S.C. § 300jj-11(b)(1), improving the quality of health care (continued...)

HITECH Act authorizes the National Coordinator—the “head of [ONC]”⁶ — to conduct several statutorily assigned tasks.⁷

First, the National Coordinator is authorized to “review and determine” whether to “endorse” certain “standard[s], implementation specification[s], and certification criteri[a]” regarding the exchange and use of health information as recommended by the Health Information Technology (HIT) Standards Committee.⁸ The HIT Standards Committee is established under section 3003 of the Public Health Service Act (PHSA) and is charged with making recommendations regarding “standards implementation specification, and certification criteria for the electronic exchange and use of health information” to the National Coordinator.⁹ In turn, under section 3004 of the PHSA, within 90 days of receiving “standards, implementation specifications, or certification criteria” that the National Coordinator has endorsed, the Secretary of HHS, in consultation with other relevant agencies, must determine whether or not to propose adoption of the endorsed policy.¹⁰ If an endorsed policy is formally proposed for adoption by the Secretary, the proposal is then subject to the general requirements for rulemaking under the Administrative Procedure Act, including notice and comment rulemaking.¹¹

The import of the phrase “standards, implementation specifications, and certification criteria” is established elsewhere in the HITECH Act. Specifically, in section 3001(c)(5) of the PHSA, the National Coordinator is authorized to “keep or recognize a program or programs for the voluntary certification of [HIT] as being in compliance with applicable certification criteria”¹² The HITECH Act further defines “certification criteria” as the “criteria” that “establish[es]” that HIT “meets” “standards and implementation specifications.”¹³ HIT is a term of art broadly defined by the Act to mean “hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance access, or exchange of health information.”¹⁴ In other words, the HITECH Act gives ONC relatively broad authority to promote the use and exchange of electronic information through a certification program that helps ensure that various health information technologies comply with HIT standards and implementation specification promulgated by HHS.

In practice, ONC’s certification criteria have been targeted at electronic health record (EHR) technology,¹⁵ a subcategory of HIT that is focused on electronic records of health-related information about an

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through the exchange and use of health information, *id.* (b)(2), (6)-(9), (11), reducing health care costs, *id.* (b)(3), and improving the informed health care decisions of the public, *see id.* (b)(4)-(5).

⁶ *See* 42 U.S.C. § 300jj(11).

⁷ *See id.* § 300jj-11(c).

⁸ *Id.* (c)(1). The National Coordinator has 45 days to act on a recommendation. *Id.* (c)(1)(B).

⁹ *See* 42 U.S.C. § 300jj-13(a). The HIT Standards Committee’s work is a product of the work of another committee established under section 3002 of the PHSA, the HIT Policy Committee. *See* 42 U.S.C. § 300jj-14(a). The HIT Policy Committee is generally tasked with making recommendations respecting a “policy framework for the development and adoption of a nationwide health information technology infrastructure that permits the electronic exchange and use of health information . . .”, with the specific duty of having to identify the “areas in which standards, implementation specifications, and certification criteria are needed” *See* 42 U.S.C. § 300jj-12(b).

¹⁰ *See* 42 U.S.C. § 300jj-14(a).

¹¹ *Id.* (a)(2)(A) (citing 5 U.S.C. § 553).

¹² *See* 42 U.S.C. § 300jj-11(c)(5)

¹³ *See id.* (c)(5)(B).

¹⁴ *See id.* § 300jj(5).

¹⁵ *See, e.g.*, 79 FED. REG. 52,910 (Sept. 4, 2014)

individual that includes “patient demographic and clinical health information” and has the “capacity . . . to provide clinical decision support, . . . to support physician order entry, . . . to capture and query information relevant to health care quality, . . . and . . . to exchange electronic health information with , and integrate such information from other sources.”¹⁶ Specifically, ONC has confined its regulatory activity to supporting the Medicare and Medicaid EHR incentive programs established by the HITECH Act, which provide an eligible health care provider, such as a physician or an acute-care hospital,¹⁷ with certain “incentive payments” if the provider can demonstrate meaningful use of EHR technology that is certified “pursuant to [PHSA] section 3001(c)(5) . . . as meeting standards adopted under section 3004” by HHS.¹⁸

Importantly, an entity’s failure to use EHR technology that does not comply with the “certification criteria, standards, and implementation specifications” enacted pursuant to the HITECH Act generally results in one consequence: the inability for that entity to obtain benefits through the incentives established under the ARRA. Put another way, ONC’s “certification criteria, standards, and implementation specifications” do *not* broadly create rules of law with civil or criminal penalties that could result from a violation of an underlying rule.¹⁹ Likewise, pursuant to section 3006(a)(2) of the PHSA, the HITECH Act generally does not provide any federal agency, including the ONC, with the authority “to require a private entity to comply with . . . a standard or implementation specification.”²⁰

¹⁶ See 42 U.S.C. § 300jj(1)&(13).

¹⁷ Eligible entities includes eligible professionals, hospitals, and Medicare Advantage organizations. See Pub. L. 111-5, 123 Stat. 115, 467, §§ 4101-4102, 4201.

¹⁸ See, e.g., *id.* § 4101 (codified at 42 U.S.C. § 1395w-4(o)(1)(A)(ii) (Medicare); *id.* § 4201 (codified at 42 U.S.C. § 1396b(t)(5)(D)) (Medicaid)). The ARRA also authorized downward payment adjustments under Medicare, beginning in 2015, for eligible entities that are not meaningful users of certified EHR technology. See *id.* § 4101 (codified at 42 U.S.C. § 1395w-4(a)(7)). In addition to the Medicare and Medicaid incentive programs, HIT certification is the lynchpin for other incentive programs established under subtitle B of the HITECH Act. For example, in order to “assist health care providers to adopt, implement, and effectively use” certified EHR technology, subtitle B of the HITECH Act requires that the Secretary of HHS invest in infrastructure “necessary to allow for and promote” the effective exchange and use of health information, including the “development and adoption” of EHR technology. See 42 U.S.C. § 300jj-31(a); see also *id.* § 300jj-31(d) (requiring that the Secretary ensure that funds expended under section 3011 be devoted to the acquisition of HIT that meet “applicable standards adopted under section 3004.”). Moreover, the Act also requires the Secretary to establish a “Health Information Technology Research Center” and “Health Information Technology Regional Extension Centers” that collectively provide “technical assistance” and develop and recognize “best practices” in order promote the effective exchange of electronic information and the use of information that is in “compliance with” HIT standards, specifications, and certification criteria adopted by the Secretary. See *id.* § 300jj-31(b)-(c). The HITECH Act also authorizes the Secretary of HHS, through ONC, to award grants of money geared toward promoting compliance with ONC’s certified criteria. See, e.g., *id.* § 300jj-33 (authorizing the awarding of planning and implementation grants to “State or qualified State-designated entities” to “promote” HIT); *id.* § 300jj-34 (authorizing the awarding of competitive grants to states and Indian tribes for the development of loan programs to facilitate the widespread adoption of certified EHR technology); *id.* § 300jj-35 (authorizing the awarding of grants to “carry out demonstration projects to develop academic curricula integrating certified EHR technology in the clinical education of health professionals.”). Importantly, the appropriations for the incentive programs established under subtitle B of the HITECH Act were limited to fiscal years 2009 through 2013. See *id.* § 300jj-38. In contrast, incentive payments under the ARRA’s Medicare and Medicaid EHR incentive program can occur through the year 2016. See Pub. L. 111-5, 123 Stat. 115, 467-68, § 4101.

¹⁹ See 42 U.S.C. § 300jj-16(a)(1) (“[N]othing in such Act or in the amendments made by such Act shall be construed . . . to require a private entity to adopt or comply with a standard or implementation specification adopted under section 3004”).

²⁰ *Id.* § 300jj-16(a)(2). There is a limited exception to the rule of construction outlined in section 3006 PHSA, in that pursuant to section 13112 of the HITECH Act, an agency must require in “contracts or agreements with health care providers, health plans, or health insurance insurers” that the entity contracting with the federal government “utilize, where available, [HIT] systems and products that meet the standards and implementation specifications adopted under section 3004 of the [PHSA]” See Pub. L. 111-5, 123 Stat. 115, 243, § 13112. While violating a provision of a federal contract requiring adherence to HIT standards and implementation mechanisms could result in collateral consequences—such as the payment of damages resulting from a breach of contract—the resulting authority provided to the federal government is limited in scope. Section 3006(b) of the PHSA states that nothing in the HITECH Act “shall be construed to require that a private entity that enters into a contract with the Federal (continued...)”

Beyond endorsing “certification criteria, standards, and implementation specifications” to promote the use and exchange of electronic health information, ONC has a number of more limited ministerial duties under the HITECH Act. For example, the National Coordinator is authorized to “coordinate health information technology policy and programs” of HHS with “those of other relevant executive agencies” in order to “avoid[] duplication of efforts.”²¹ In addition, ONC is charged with updating and publishing the “Federal Health IT Strategic Plan,”²² a policy document that describes the federal government’s strategy—including “specific objectives, milestones, and metrics”²³—to improve health and health care through the use of health information and technology.²⁴ Moreover, the National Coordinator is obligated to submit five different reports: (1) assessing the current funding and legal authority for the ONC; (2) identifying “lessons learned” from private and public health care systems that use health information technology; (3) assessing the impact of health information technology on “communities with health disparities and in areas with a high proportion of individuals who are uninsured, underinsured, and medically underserved;” (4) evaluating the costs and benefits of the electronic use and exchange of health information; and (5) estimating and publishing the “resources required annually to reach the goal of utilization of an electronic health record for each person in the United States by 2014”²⁵ The ONC is also authorized to provide financial assistance to certain “consumer advocacy and not-for-profit entities that work in the public interest” in order to “defray the cost to such groups and entities” so that they can participate under the National Technology Transfer Act of 1995.²⁶ ONC must also “maintain and frequently update an Internet website” containing information on the work of the ONC, including any reports or recommendations the agency issues.²⁷ Finally, section 3007 of the PHSA allows the ONC to “support the development and routine updating” of EHR technology and to “make available” certified EHR technology to the public.²⁸

Health IT Safety Center Proposal

Acting pursuant to section 618 of the Food and Drug Administration Safety and Innovation Act (FDASIA),²⁹ in April of 2014, FDA, FCC, and ONC jointly published a report, which, in relevant part,

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Government apply or use the standards and implementation specifications . . . with respect to activities *not* related to the contract. 42 U.S.C. § 300jj-16. It should be noted that the HITECH Act authorizes the National Coordinator to “establish a governance mechanism for the nationwide health information network,” *see id.* § 300jj-11(c)(8), but nowhere does the statute define what a “governance mechanism” entails.

²¹ *See* 42 U.S.C. § 300jj-11(c)(2).

²² *Id.* (c)(3).

²³ *Id.*

²⁴ *See* ONC, *Federal Health IT Strategic Plan Progress Report*, July 19, 2013, available at, <http://www.healthit.gov/policy-researchers-implementers/federal-health-it-strategic-plan-progress-report>. The HITECH Act outlines some specific subjects that the Federal Health IT Strategic Plan must discuss, including the “electronic exchange and use of health information and the enterprise integration of such information.” *See* 42 U.S.C. § 300jj-11(c)(3) (A)(i)-(vii). In addition, the PHSA mandates that the National Coordinator “review Federal health information technology investments” to ensure that “Federal health information technology programs” are compliant with the objectives of the strategic plan. *See id.* (c)(1)(C).

²⁵ *Id.* (c)(6)(A)-(E).

²⁶ *Id.* (c)(7). The National Technology Transfer Act of 1995 mandates that all federal agencies use technology standards developed and adopted by voluntary consensus standard bodies. *See* 15 U.S.C. § 272 note.

²⁷ *See* 42 U.S.C. § 300jj-11(c)(4).

²⁸ *See* 42 U.S.C. § 300jj-17(a)-(b). The ONC is authorized to charge nominal fees for the adoption of technology made available under section 3007 of the PHSA, *see id.* § 300jj-17(c), but section 3007 cannot be construed as an affirmative source of authority to require that a private or governmental entity must adopt or use certified EHR technology, *see id.* § 300jj-17(d).

²⁹ *See* Pub. L. 112-144, § 618(a).

proposed the “creation of a Health IT Safety Center.”³⁰ The Health IT Safety Center proposal, as described in the report, would be a “public-private entity” “created by ONC” that would “convene stakeholders in order to focus on activities that promote” HIT.³¹ The “ultimate goal” for the Safety Center is to “creat[e]” a “learning system” that “avoids regulatory duplication and leverages and complements existing and ongoing efforts.”³² While the FDASIA Report is short on specifics as to the exact role of the Health IT Safety Center, the Report does note that the Safety Center “will require a strong governance mechanism and involvement by participants in programs and activities” that (1) “[e]stablish a broad and engaged stakeholder membership and leadership base;” (2) “[f]ocus on high-value issues” respecting HIT; (3) analyze the “best available data and evidence” respecting HIT safety; (4) “create or inform [HIT] priority goals and measures that align with broader patient safety goals and initiatives;” and (5) “[p]rovide education on [HIT] safety”³³

In May of 2014, the Director of the Office of Policy and Planning for ONC, in a presentation (herein May 2014 Presentation) on the April 2014 Report, further elaborated on the Health IT Safety Center proposal.³⁴ In the Director’s May 2014 Presentation, the Safety Center was described as a “public-private entity” that would “serve as a trusted convener of [HIT] stakeholders and identify the governance structures and functions needed for the creation of a sustainable, integrated [HIT] learning.”³⁵ However, the precise contours of the Health IT Safety Center remained undefined, as the presentation actively asked for “input” as to the Safety Center’s “governance structure” and “functions.”³⁶

In August of 2014, following a meeting one month earlier,³⁷ the HIT Policy Committee provided the National Coordinator with a host of recommendations for the Health IT Safety Center, broadly suggesting that the Center provide a “non-regulatory role and focus on recommendations for [HIT] policy and standards,” with an emphasis on “learning, not enforcement.”³⁸ In this vein, the Policy Committee recommended that the “key functions” of the Safety Center could include serving as a “Clearinghouse for HIT safety-related theories and ideas for best practices.”³⁹ The Policy Committee also suggested that the Safety Center should “review . . . evidence” from stakeholders and “partner with other organizations . . . that conduct investigations” regarding HIT adverse events.⁴⁰ The August 2014 recommendations from the Policy Committee envisioned the Health IT Safety Center “start[ing] small in scope and gradually grow[ing].”⁴¹

³⁰ FDASIA Report at 4.

³¹ *Id.*

³² *Id.* at 14.

³³ *Id.* at 14-15.

³⁴ See Jodi G. Daniel, *FDASIA Health IT Report*, May 6, 2014, available at http://www.healthit.gov/facas/FACAS/sites/faca/files/HITPC_FDASIA_Overview_2014-05-06.pptx (herein May 2014 Presentation).

³⁵ *Id.* at 15-16.

³⁶ *Id.* at 17.

³⁷ See Health IT Policy Committee, *Safety Task Force*, July 7, 2014, available at http://www.healthit.gov/facas/sites/faca/files/HITPC_STF_%20Report_Recommendations_2014-07-08.pdf

³⁸ See Paul Tang, *Letter to National Coordinator Karen DeSalvo*, August 4, 2014, at pg. 2, available at http://www.healthit.gov/facas/sites/faca/files/STF__Safety_Center_Transmittal_2014-08-05.pdf.

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.* at 3.

In September of 2014, ONC issued a report entitled “ONC Health IT Safety Program –Progress on Health IT Patient Safety Action and Surveillance Plan.”⁴² In the September report, ONC disclosed that it had solicited offers for developing a road map for the Safety Center and that the awarding of such a contract would occur by the end of September.⁴³ News reports from early October indicated that ONC awarded a contract to RTI International in order to develop a road map for a potential Health IT Safety Center.⁴⁴ In turn, RTI International released a document entitled “Health IT Safety Center Road Map Task Force (“RTI Road Map”),” which includes a “summary of operational considerations for a potential Health IT Safety Center[.]”⁴⁵ In particular, in the RTI Roadmap, the contractor lists seven different “potential core activities” for the Health IT Safety Center, including “provid[ing] educational programs about research and activities;” “analyz[ing] evidence on HIT safety and safety tool/interventions” and producing written reports; and identifying HIT safety research “goals, priorities and related measures.”⁴⁶ RTI International’s summary also includes several “boundaries on the scope” of the Health IT Safety Center’s activities, including that the Safety Center will not “engage in direct investigation or surveillance,” perform “direct data collection,” or exercise regulatory authority.⁴⁷ The RTI Road Map envisions “developing, vetting, finalizing, and submitting” a final Road Map on the Safety Center to ONC in the spring of 2015.⁴⁸

ONC’s Authority to Create a Health IT Safety Center

The determination of whether ONC has the authority to create the Health IT Safety Center, as with any question respecting the scope of an administrative agency’s authority to undertake a certain action, ultimately turns on the specifics of the action the agency is considering coupled with the “nature and scope of the authority granted by Congress to the agency.”⁴⁹ Unfortunately, it is very difficult to ascertain the precise contours of ONC’s proposed Safety Center because of both the somewhat cryptic nature in which the Health IT Safety Center has been described thus far by the agency and because of the tentative nature of the proposal.

To date, the ONC’s descriptions and discussion of the proposed Health IT Safety Center has at times been vague and imprecise, even hinting at the possibility that the Center would have some type of regulatory role, such as having the power to establish governing rules for the HIT industry.⁵⁰ On the other hand,

⁴² See ONC, ONC Health IT Safety Program –Progress on Health IT Patient Safety Action and Surveillance Plan, Sept. 9, 2014, available at http://www.healthit.gov/sites/default/files/ONC_HIT_SafetyProgramReport_9-9-14_.pdf.

⁴³ *Id.* at 5.

⁴⁴ See Ashley Gold, *ONC laying groundwork for health IT safety center*, POLITICO, Oct. 9, 2014, available at <http://www.politico.com/morninghealth/1014/morninghealth15622.html>.

⁴⁵ See RTI Int’l, *Health IT Safety Center Road Map Task Force*, available at http://www.healthitsafety.org/uploads/4/3/6/4/43647387/health_it_safety_center_scope_final.pdf (hereinafter “RTI Road Map”).

⁴⁶ See *id.* at 2. Other goals included: (1) promoting opportunities for engagement in HIT related safety activities and programs in the public sector; (2) fostering health IT safety research and development in the private sector and by government; (3) encouraging stakeholders to measure, evaluate, and share progress related to identified goals respecting HIT; and (4) provide a forum for private-sector stakeholders and Federal Government representatives to dialogue and work together. *Id.*

⁴⁷ See *id.* at 3-4.

⁴⁸ *Id.* at 5.

⁴⁹ See *La. Public Serv. Comm’n v. FCC*, 476 U.S. 355, 374 (1986).

⁵⁰ For example, the April 2014 Report envisions the Health IT Safety Center as “creat[ing] . . . [a] system that avoids regulatory duplication” and “creat[ing] . . . measures that align with broader patient safety goals and initiatives,” a role that presumably would have the Center promulgate and repeal rules respecting HIT to create a coherent regulatory regime. See FDASIA Report at 14-15. More particularly, the April 2014 Report, *see id.* at 14, the May 2014 Presentation, *see* May 2014 Presentation at 5 (“Implement IOM Health IT safety recommendations to create a ‘learning environment’ . . . Cross-agency group should establish governance of Health IT safety.”), and the August recommendations from the Policy Committee, *see* Paul Tang, *Letter to* (continued...)

other statements by ONC and RTI International explicitly preclude the Safety Center from having a regulatory function, and instead envision the Health IT Safety Center as an informal clearinghouse where public and private entities can broadly share ideas on HIT.⁵¹

While the seemingly conflicting and vague language respecting the role envisioned for the Health IT Safety Center may ultimately reflect the fact that the Safety Center is still largely undefined,⁵² the plain language of the HITECH Act appears to foreclose any regulatory role for the Safety Center. After all, the HITECH Act specifically limits the authority provided under the Act, in that the statute cannot be construed to “require a private entity to adopt or comply with a standard” proposed by ONC and promulgated by HHS under section 3004 of the PHSA.⁵³ Likewise, under section 3006(a)(2) of the PHSA, the HITECH Act generally does not provide any federal agency, including the ONC, with the authority “to require a private entity to comply with . . . a standard or implementation specification.”⁵⁴ As noted above, ONC’s statutory role is largely centered on proposing “standards, implementation specifications, and certification criteria” that form the basis for several incentive programs established under the ARRA to encourage, rather than require, entities to adopt certified HIT.⁵⁵

Putting to the side the possibility that the proposed Safety Center would have a robust regulatory role, the question remains as to whether ONC can establish a Health IT Safety Center that takes on the more modest role of a clearinghouse or a public-private partnership. Importantly, in determining whether an agency has the power to take a particular action, one should not search for a statutory prohibition, and conclude from the absence of such a prohibition that the agency can take an affirmative act.⁵⁶ Instead, as the Supreme Court has repeatedly noted “an agency literally has no power to act . . . unless and until

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National Coordinator Karen DeSalvo, August 4, 2014, at pg. 3, available at http://www.healthit.gov/facas/sites/faca/files/STF__Safety_Center_Transmittal_2014-08-05.pdf, envision the Health IT Safety Center as having a “strong” and “gradually grow[ing]” “governance mechanism,” language that could imply that the Safety Center will be taking robust regulatory action with respect to HIT. See WEBSTER’S THIRD NEW INT’L DICTIONARY 982 (1976) (defining governance as “the act or process of governing”); see also BALLENTINE’S LAW DICTIONARY (3d ed. 2010) (defining “govern” as “to direct and control; to regulate; to influence; to restrain; to manage”).

⁵¹ For example, the April 2014 Report and the May 2014 Presentation describe the Safety Center as a “trusted convener of health IT stakeholders,” see FDASIA Report at 14; see also May 2014 Presentation at 15, a moniker that implies that the Health IT Safety Center’s role is limited to merely assembling various HIT stakeholders in a central location. See WEBSTER’S THIRD NEW INT’L DICTIONARY 497 (1976) (defining “convener” as “one that convenes, esp. the chairman of a committee or other organized body of persons.”); see also BALLENTINE’S LAW DICTIONARY (3d ed. 2010) (defining “convene” as “to assemble; to meet as a body; to call a meeting”). And in a July 2014 letter to the House Committee on Energy and Commerce, the National Coordinator of ONC explicitly states that the April 2014 Report “did not propose that the Health IT Safety Center would have the authority to regulate health IT.” See Karen B. DeSalvo, Letter to The Honorable Fred Upton, Chariman, Committee on Energy and Commerce, July 8, 2014, at pg. 2, available at <http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/letters/20140708ONCresponse.pdf> (hereinafter “July 2014 Letter”). The July 2014 letter is echoed by the August 2014 suggestions from the Policy Committee that envision the Safety Center as operating in a “non-regulatory role,” see Paul Tang, Letter to National Coordinator Karen DeSalvo, August 4, 2014, at pg. 2, available at http://www.healthit.gov/facas/sites/faca/files/STF__Safety_Center_Transmittal_2014-08-05.pdf, and by the RTI Road Map which explicitly states that the Health IT Safety Center will not “exercise . . . regulatory authority.” See RTI Road Map at 3.

⁵² *Id.* at 5 (noting that the exact details for a proposed Health IT Safety Center is still a work-in-progress).

⁵³ See 42 U.S.C. § 300jj-16(a)(1) (“[N]othing in such Act or in the amendments made by such Act shall be construed . . . to require a private entity to adopt or comply with a standard or implementation specification adopted under section 3004”).

⁵⁴ *Id.* § 300jj-16(a)(2). It should be noted that the HITECH Act authorizes the National Coordinator to “establish a governance mechanism for the nationwide health information network,” see *id.* § 300jj-11(c)(8), but nowhere does the statute define what a “governance mechanism” entails.

⁵⁵ See *supra* “ONC and its Current Legal Authority.”

⁵⁶ See *Fag Italia S.P.A. v. United States*, 291 F.3d 806, 816 (Fed. Cir. 2002).

Congress confers power upon it.”⁵⁷ Accordingly, agencies are a “creature of statute, and may act only because, and only to the extent that, Congress affirmatively has delegated them the power to act.”⁵⁸

Applying this principle to the instant matter, even if ONC does not foresee the Health IT Safety Center as taking on a regulatory role—an act that is specifically prohibited by the HITECH Act—and instead merely envisions the Safety Center as being either a clearinghouse or a private-public partnership that collects and disseminates information on HIT matters, ONC cannot legally engage in such activity without an affirmative grant of authority from Congress.⁵⁹ The operative question, therefore is whether ONC can point to any affirmative grants of authority that either implicitly or explicitly authorize the establishment of a wholly new public-private entity that acts as a national clearinghouse on HIT issues, including perhaps providing educational programs or issuing analytical reports on HIT matters.

In the July 2014 letter to the House Committee on Energy and Commerce, the National Coordinator pointed to three statutory provisions to demonstrate that Congress had affirmatively granted the agency the authority to establish the Health IT Safety Center. First, the National Coordinator argued that Congress authorized the establishment of the Safety Center though section 3001(b) of the PHSA,⁶⁰ which broadly discusses the “purposes” of the National Coordinator.⁶¹ Specifically, the letter cited section 3001(b)(11),⁶² which states that the “National Coordinator shall perform the duties under subsection (c) in a manner consistent with the development of a nationwide [HIT] infrastructure that allows for the electronic use and exchange of information and that – promotes a more effective marketplace, greater competition, greater systems analysis”⁶³

Section 3001(b)(11), however, may be a thin reed on which to base the establishment of the Safety Center. While Congress need not expressly delegate every action in order for an agency to lawfully take a specific action,⁶⁴ agency action must necessarily follow from, and be consistent with, the operative governing legislation,⁶⁵ and an agency cannot take action merely because a statute is broadly or ambiguously worded.⁶⁶ More specifically, courts have rejected reading a statute’s broad purposes as a source of authority for an agency, particularly where Congress has explicitly delineated the boundaries of an agency’s authority elsewhere in a statute.⁶⁷ With respect to the PHSA, Congress announced the broad

⁵⁷ See *La. Pub. Serv. Comm’n*, 476 U.S. at 374; see also *Lyng v. Payne*, 476 U.S. 926, 937 (1986) (“[A]n agency’s power is no greater than that delegated to it by Congress.”); *American Fin. Servs. Ass’n v. FTC*, 767 F.2d 957, 965 (D.C. Cir. 1985) (“The extent of [an agency’s] powers can be decided only by considering the powers Congress specifically granted it in the light of the statutory language and background.”).

⁵⁸ *American Bus Ass’n v. Slater*, 231 F.3d 1, 9 (D.C. Cir. 2000) (Santelle, J., concurring).

⁵⁹ See *American Fin. Servs. Ass’n*, 767 F.2d at 965 (holding that an agency’s power can only be decided by considering the “powers Congress specifically granted it in the light of the statutory language and background.”) (emphasis added).

⁶⁰ See July Letter at 2.

⁶¹ 42 U.S.C. § 300jj-11(b)(10).

⁶² See July Letter at 2.

⁶³ 42 U.S.C. § 300jj-11(b)(10).

⁶⁴ See *Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457, 472 (2002) (holding that Congress need only lay down an “intelligible principle” to an agency); see also *Morton v. Ruiz*, 415 U.S. 199, 231 (“The power of an administrative agency to administer a congressionally created . . . program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress.”).

⁶⁵ See *Ruiz*, 415 U.S. at 232.

⁶⁶ See *Michigan v. EPA*, 268 F.3d 1075, 1082 (D.C. Cir. 2001) (“Mere ambiguity in a statute is not evidence of congressional delegation of authority.”).

⁶⁷ See *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 261 (1993); see also *Platte River Whooping Crane Critical Habitat Maint. Trust v. FERC*, 295 U.S. App. D.C. 218, 962 F.2d 27, 33 (D.C. Cir. 1992); see generally *MCI Telecomms. Corp. v. AT&T Co.*, 512 (continued...)

purposes of the role of the National Coordinator in section 3001(b), but explicitly tied those broad purposes to the duties the National Coordinator possesses under section 3001(c).⁶⁸ Put another way, section 3001(b) broadly outlines the general goals envisioned for the National Coordinator, but the plain language of the HITECH Act indicates that section 3001(b) was not meant to be a source of authority for National Coordinator's actions.

Perhaps acknowledging the limits of attempting to establish the Health IT Safety Center based on the language in section 3001(b)(11) of the PHS Act, the July 2014 letter cites to PHS Act section 3001(c)(5) as an additional source of authority for ONC to establish the Safety Center.⁶⁹ As discussed above, section 3001(c)(5) authorizes ONC to “keep or recognize” a program respecting the “voluntary certification” of HIT, allowing HIT articles to be certified as being compliant with certain certification criteria, which in turn are based on standards and implementation specifications recommended by the HIT Standards Committee and promulgated by the Secretary of HHS.⁷⁰ While section 3001(c)(5), unlike section 3001(b), is an affirmative grant of authority to ONC, the plain terms of section 3001(c)(5) appear to be limited to authorizing ONC to establish a HIT certification program and do not appear to discuss the concept of ONC establishing and running a national clearinghouse or public-private partnership on HIT matters.⁷¹ Section 3001(c)(5) does not appear, for example, to explicitly or even implicitly authorize ONC to run an education program or issue reports from a Safety Center, but instead the section is focused on the issue of HIT certification. Moreover, the HITECH Act already establishes advisory committees composed of stakeholders, such as the HIT Policy Committee⁷² and the National Committee on Vital and Health Statistics,⁷³ and a rulemaking process that itself requires stakeholder comment and input.⁷⁴ It is unclear why ONC has authority based on section 3001(c)(5) to establish an *additional* means of facilitating input from private industries on HIT issues. As one court has noted, “when Congress has made an explicit delegation of authority to an agency, Congress did not intend to delegate additional authority *sub silentio*,”⁷⁵ meaning that section 3001(c)(5) cannot be read so expansively as to provide ONC with powers that the section simply does not contemplate.

Finally, the July 2014 letter suggests that PHS Act section 3011 provides a basis for the ONC's authority to establish the Health IT Safety Center.⁷⁶ Section 3011, which authorizes funding to strengthen HIT infrastructure, is one of several new HIT grant, loan, and demonstration programs established under subtitle B of the HITECH Act.⁷⁷ Specifically, section 3011 authorizes the Secretary, “using amounts

(...continued)

U.S. 218, 231 n.4 (1994) (holding that agencies are bound “not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes.”).

⁶⁸ 42 U.S.C. § 300jj-11(b) (“The National Coordinator shall perform the duties *under subsection (c)* in a manner consistent”) (emphasis added).

⁶⁹ See July 2014 Letter at 2.

⁷⁰ See *supra* “ONC and its Current Legal Authority” at 2-3.

⁷¹ While the HITECH Act contemplates public and private collaboration on HIT issues, the context of such collaboration and the authority provided to ONC with respect to coordinating such collaboration appears to be limited on the face of the statute. See, e.g., 42 U.S.C. § 300jj-11(c)(3)(B) (authorizing ONC to publish a HIT strategic plan that is “updated through collaboration of public and private entities”); see also 42 U.S.C. § 300jj-31(b) (authorizing the Secretary to “create a [HIT] Research Center” whose purpose is – in part—to “accelerate the transfer of lessons learned from existing public and private sector initiatives”).

⁷² See 42 U.S.C. § 300jj-12.

⁷³ See 42 U.S.C. § 242k; see also *id.* § 300jj-12 (c)(8); *id.* § 300jj-13(b)(5).

⁷⁴ See 42 U.S.C. § 300jj-14(a)(2)(A).

⁷⁵ *Texas v. United States*, 497 F.3d 491, 503 (5th Cir. 2007).

⁷⁶ See July Letter at 3 (“In addition, PHS Act section 3011”).

⁷⁷ See 42 U.S.C. §§ 300jj-31 – 300jj-37.

appropriated under section 3018,” to invest in HIT infrastructure “necessary to allow for and promote the electronic exchange and use of health information for each individual in the United States”⁷⁸ Section 3011 funds must be invested by the Secretary of HHS through “different agencies with expertise,” including ONC for several purposes, including the “promotion of technologies and best practices that enhance the protection of health information”⁷⁹ While the establishment of a HIT clearinghouse by ONC may arguably be an investment in HIT “infrastructure” that promotes “best practices that enhance the protection of health information,”⁸⁰ it is unclear whether the HITECH Act as currently written authorizes the establishment of a Health IT Safety Center based on section 3011. The plain language of section 3011 limits the use of funds to those “appropriated under section 3018,”⁸¹ which in turn states that “[f]or the purposes of carrying out [subtitle B of the HITECH Act]” – which necessarily includes section 3011 – appropriated sums are authorized “for each of the fiscal years 2009 through 2013.”⁸² In other words, it is difficult to see how section 3011 authorizes ONC to establish a Health IT Safety Center in the year 2014 or thereafter, when the plain terms of section 3011 are temporarily limited to fiscal years 2009 through 2013.⁸³

In short, the July 2014 letter from ONC does not appear to provide a clear basis for why the agency has the authority to establish a Health IT Safety Center, even if that entity acts in a non-regulatory capacity. While perhaps other parts of the HITECH Act or other laws authorize ONC to establish the Safety Center, many of ONC’s statutory authorities are either (1) tied to incentive programs that are limited in scope or have expired or (2) are purely ministerial in nature.⁸⁴ More to the point, the agency has not suggested any other sources of law authorizing the creation of the Health IT Safety Center, and if the agency were to solely rely on the three legal sources identified in the July 2014 letter, legal questions could arise with respect to ONC’s authority to establish the Safety Center.⁸⁵ Nonetheless, as discussed earlier, because the exact nature of Health IT Safety Center is unknown and because ONC’s legal justifications for the Safety Center may change or may become more refined, a definitive conclusion as to the legality of the proposed Health IT Safety Center is not possible in this memorandum.

⁷⁸ See 42 U.S.C. § 300jj-31(a).

⁷⁹ *Id.* § 300jj-31(a)(6).

⁸⁰ *Cf.* BLACK’S LAW DICTIONARY (9th ed. 2009) (defining infrastructure as “[t]he underlying framework of a system; esp., public services and facilities (such as highways, schools, bridges, sewers and water systems) needed to support commerce as well as economic and residential development”).

⁸¹ See 42 U.S.C. § 300jj-31(a).

⁸² *Id.* § 300jj-38.

⁸³ An agency cannot act other than by appropriation from Congress, *see* *Environmental Defense Ctr. v. Babbitt*, 73 F.3d 867, 871-72 (9th Cir. 1995), and if the agency expends any resources – such as salaries, employees, paper, or buildings – to accomplish a particular task, such expenditures need to be a product of an appropriation by Congress. *Id.*; *see also* *United States Dep’t of the Navy v. Fed. Labor Rels. Auth.*, 665 F.3d 1339, 1347 (D.C. Cir. 2012) (holding that Congress’ “control over federal expenditures is ‘absolute’” and an agency is not authorized to make “expenditure[s] of funds beyond what Congress has approved.”); *see also* *Highland Falls-Fort Montgomery Cent. Sch. Dist. v. United States*, 48 F.3d 1166, 1171, 1172 (Fed. Cir. 1995) (same) (citing 31 U.S.C. § 1341(a)(1)(A) & 31 U.S.C. § 1532)

⁸⁴ See *supra* “ONC and its Current Legal Authority” at 3-4.

⁸⁵ As such, this memorandum is not meant to suggest that the establishment of the Safety Center would be unlawful, as such a conclusion would necessitate proving the “negative” that no laws exist in the corpus of American law that authorize ONC’s conduct. Instead, the memorandum merely concludes that the July 2014 letter from ONC has not provided a clear source of authority for establishing the Health IT Safety Center.