Commentary

Expanding Contracting Authorities Across the Department of Health and Human Services Family of Agencies to Address Critical Public Health Needs

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The COVID-19 pandemic revealed gaps in the Department of Health and Human Services' (HHS) contracting authorities that limited rapid expansion of medical countermeasure (MCM) services, such as no-cost COVID-19 testing. The CDC's Increasing Access To Community Testing (ICATT) program initially used temporary waivers to quickly partner with non-traditional pharmacy vendors, enabling more than 10,000 community testing sites. When these waivers were later discontinued, many vendors could no longer qualify for federal contracts, resulting in the loss of over 1,700 sites and blocking access to thousands more potential locations. These challenges stem from the absence of broad, department-wide Other Transaction Authorities (OTAs) within HHS, which would allow flexible agreements similar to those used effectively by the Department of Defense. Although a few HHS agencies hold limited OTAs, none are authorized to acquire MCM service capabilities such as testing. Expanding OTA authority across HHS, and explicitly including MCM services, would enable faster, more adaptable engagement with non-traditional partners during public health emergencies. Establishing department-level OTA policy, training, and guidance would further strengthen national preparedness and ensure more resilient responses in future crises.

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Expanding No-Cost COVID-19 Testing Services

In January 2021, the U.S. Centers for Disease Control (CDC) Increasing Community Access to Testing (ICATT)[1] program needed to rapidly expand COVID-19 testing to commercial pharmacies to improve

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access to testing in communities disproportionately affected by COVID-19, those in rural regions, and in high Social Vulnerability Index (SVI) areas. The goal was to establish 10,000 pharmacy sites that prioritized providing no-cost COVID-19 testing in these communities. The challenge associated with this goal was that many potential pharmacy vendors had no prior experience contracting with the Federal government. As a result, they would require special contracting accommodations, such as waivers, to be eligible for consideration for these opportunities. To meet this goal, the ICATT program leveraged Federal Acquisition Regulation (FAR) waivers sanctioned under the Department of Health and Human Services (HHS) Public Health Emergency (PHE) authorities[2] and rapidly awarded sole-source (i.e., non-competed) contracts to four commercial pharmacies. By November 2021, these pharmacy partners had opened more than 10,000 testing sites. However, due to surging demand, more sites were still needed, and a new goal was set to scale up to 20,000 test sites. For ICATT to rapidly expand testing in disproportionately affected communities, the program needed to partner with existing retail vendors who maintain large footprints in these communities. With this shift in focus, the contracting strategy also changed from awarding non-competitive contracts (i.e., using the waivers) to competitive bidding processes, which would help secure better prices and more convenient test site locations. Unfortunately, this change meant that some potential vendors, who could have opened many more test sites, were excluded because they could not meet the complex federal rules for contracts, like certain accounting standards. As a result, the ICATT program had fewer options for expanding the testing network.

Per Congressional statutory authorities, in a declared PHE, HHS may waive certain FAR contract compliance clauses[3], which HHS did in 2021 when it awarded the four sole-source contracts. However, in 2022 when it was time to recompete the contracts, HHS leadership decided (based on contracting strategy decisions not publicly disclosed) not to waive the FAR clauses, and thus ICATT-sponsored COVID-19 testing at 1,700+ pharmacies (some in rural and high SVI areas) was discontinued. Moreover, without these waivers ICATT could not leverage retail vendors, such as Dollar General and Kroger, to expand testing to their 18,000+ available locations. Without codified access to FAR clause waivers, the ICATT contracting office was not authorized to deviate from the FAR[3], resulting in the ICATT program facing an insurmountable barrier to rapidly expand the program's site locations without being able to access additional pharmacy vendors.

Expanding The Department of Health and Human Services Contracting Authorities

The COVID-19 pandemic revealed shortfalls in statutory contracting authority within the Department of Health and Human Services that limited access to medical countermeasure (MCM) services, such as free COVID-19 testing through commercial pharmacies, services that could have helped address critical public health security and accessibility needs. Specifically, HHS lacked the statutory authority to utilize Other Transaction Authorities[4] (OTAs) that allow agencies to enter into non-FAR agreements with industry partners. Essentially, OTAs are legally binding agreements codified in congressional statutory authority that provide the federal government with greater flexibility in engaging with a wider range of vendors, including those who have not traditionally worked with the government.[5] Expanding the agencies under the Department of Health and Human Services that have access to OTAs, along with their scope, will remove the contracting shortfalls exposed during the pandemic to enable the government to have more effective partnerships with industry.

According to a U.S. Government Accountability Office report in July 2021, "Federal contracting—including OTAs—played a critical role in the nation's response to COVID-19 by accelerating the development of vaccines and the procurement of vital goods and services. The public and congressional decision-makers must understand the significant role that OTAs play and how they can be leveraged in the future, especially if another national emergency calls for the expanded use of such tools."[6] The barrier to an agency, such as the CDC, accessing non-FAR solutions (i.e., utilizing OTAs) is that the authorities must be codified and explicitly authorized in Federal statute, including a clearly defined scope and applicability of OTAs within the context of the intended use. Unfortunately, as of the Public Law (P.L.) 117-328 Consolidated Appropriations Act 2023[7], within the HHS family of agencies only the Administration for Strategic Preparedness and Response/Biomedical Advanced Research and Development Authority (ASPR/BARDA)[8], Advanced Research Projects Agency for Health (ARPA-H)[9], and National Institutes of Health (NIH)[10] have limited statutory OTAs that enable these organizations to award contracts, grants, cooperative agreements, and enter into other transactions that pertain to improving MCM *products* (e.g., biologics, drugs, devices). However, none of these agencies' authorities explicitly authorize the federal government to acquire MCM testing *services* (e.g., free COVID-19 testing services via commercial pharmacies) outside standard FAR contracting mechanisms (e.g., NIH's authorities for research associated with prevention, diagnosis, or treatment of diseases and disorders, or research urgently

required to respond to a public health threat[10]). Up to this point in time, no OTA MCM testing services were awarded because no HHS agencies had sufficient authorities.

Recently, the CDC was granted its first-ever OTA[11] for purposes of infectious disease research, biosurveillance, infectious disease modeling, and public health preparedness and response. This new OTA provides sufficient direction to enable the CDC to acquire MCM services in support of public health preparedness and response. However, without follow-on agency guidance and training, the HHS acquisition and contracting workforce may hesitate to utilize OTAs due to concerns about insufficient leadership support and potential misinterpretation of the governing statute. In the example mentioned above, leveraging non-FAR vendor agreement solutions would have allowed the ICATT program to access and reap the full benefits of creating prototype MCM testing services that not only would have fulfilled the COVID-19 pandemic requirement, but also positioned the government to leverage these processes for future PHEs. In addition to broadening access to OTAs across the entire Department of Health and Human Services (i.e., clarifying 'who' within HHS holds these authorities), Congress must revise the statute to cover MCM services just as it has for MCM products (i.e., defining 'what' authorities can be enacted). Elevating OTAs to the department level across HHS, rather than limiting them to individual agencies, will ensure strategic and consistent access to the premier capabilities of America's health industrial base, both current and emerging, regardless of individual agency structures, priorities, or workforce limitations.

Developing The Department of Health and Human Services OTA Policies

The U.S. Department of Defense (DoD) has set a precedent for government agencies to partner with non-traditional vendors[12], enabling the rapid adoption of innovative solutions. By leveraging non-FAR solutions that are codified in statute for the DoD, they have simplified the process, allowing them to quickly move from testing new ideas to implementing them on a large scale. With an enhanced set of OTAs, HHS can strategically examine the capability gaps across MCM products ***and*** services and develop acquisition and contracting strategies that will position any one of the many agencies under their umbrella to mount a more effective response during the next health crisis.

To enhance HHS's ability to utilize OTAs for MCM services, Congress should create a new section in 42 U.S. Code Chapter 6A - Public Health Service[13] that is similar to DoD's authorities in 10 U.S. Code § 4021[14] and § 4022[15] to expand the applicability and scope of OTAs. This revised statute should include

two key components: first, replicate the existing OTAs within ASPR/BARDA, ARPA-H, NIH, and the CDC across all HHS agencies involved in research, development, prototyping, and the scaling of public health security solutions. Ideally, a unified directive at the HHS department level would create consistent and flexible OTA opportunities, ensuring their continuity and adaptability regardless of agency-level reorganizations or mission changes. This approach would mirror the DoD's OTA framework, which operates at the department level rather than being limited to individual service branches. Second, broaden the scope of these OTAs to cover not only the acquisition of MCM products but also the testing and services components essential for public health security, aligning with the CDC's current OTA framework as outlined in 42 U.S. Code § 242c[11].This updated contracting authority will grant HHS access to America's vast and innovative pool of non-traditional vendors. Revising HHS authorities will also enable HHS to establish OTA policies, align resources, and implement acquisition workforce OTA training. To fully capitalize on expanded OTAs, HHS must create and implement new policies for workforce recruitment and development, while leveraging DoD's OTA training and experience to rapidly scale up its workforce to effectively enhance OTA capabilities.

To mount a more effective public health response in future emergencies, the U.S. government must have the flexibility to collaborate with a diverse range of industry partners, both during health crises and in periods between them. Enabling HHS with overarching Other Transaction Authorities will further enable the agencies under its umbrella to contract rapidly and agilely with commercial partners, safeguarding the health and well-being of Americans.

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