UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CONEY ISLAND PREP, *et al.*,

                    Plaintiffs,

    - against -

UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES, *et al.*,

                    Defendants.

No. 20 Civ. 9144 (VM)

DECLARATION OF PERRYN ASHMORE

    I, PERRYN ASHMORE, pursuant to the provisions of 28 U.S.C. § 1746, declare, under penalty of perjury, as follows:

    1.   I am Acting Chief Information Officer ("CIO") at the United States Department of Health and Human Services ("HHS" or the "Department"). As Acting HHS CIO, I provide leadership and oversight of the information technology ("IT") systems and security activities for a workforce of over 83,000. As the head of HHS's Office of the Chief Information Officer ("OCIO"), I lead the Department's efforts in developing and implementing IT policies, managing high priority projects, and planning strategic IT investments. As the CIO, I provide leadership and oversight of the Department's $6.3 billion IT portfolio in support of its expansive mission to enhance the health and well-being of Americans.

    2.   I make this declaration based on my personal knowledge, information acquired by me in the course of performing my official duties, information provided to me by federal employees, and government records.

    3.   I have reviewed portions of documents filed in the above-captioned case, including the Complaint, Dkt. No. 1, and the Memorandum of Law in Support of Plaintiffs'

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Motion for a Preliminary Injunction, Dkt. No. 7, which concern HHS's decision to collect certain COVID-19-related data through HHS TeleTracking and to make it available at HHS Protect.

4.　　This declaration explains HHS's COVID-19 data collection from hospitals and other healthcare facilities, which has been used for epidemiological surveillance and public health decision-making during the course of this public health emergency.

CDC's National Healthcare Safety Network ("NHSN")

5.　　The National Healthcare Safety Network ("NHSN") system was created in 2005 by the Centers for Disease Control and Prevention ("CDC") to track and improve patient safety related to healthcare-associated infections, antibiotic resistant infections, and antibiotic use.

6.　　NHSN is a national surveillance system developed, maintained, and used by CDC, healthcare facilities, and state and local health departments for infection control activities, more specifically, healthcare-associated and antibiotic resistant infection surveillance, health care and clinical quality measurement of those infections, and epidemiological and statistical analysis. It is also used as the basis for multiple Centers for Medicare & Medicaid Services ("CMS") payment programs and HHS national goals, including the HHS National Action Plan to Prevent Healthcare-Associated Infections. Healthcare facilities provide their data through NHSN both voluntarily and to fulfill certain mandatory reporting requirements. These data are analyzed and used by CDC in fulfilling its statutory responsibilities to prevent healthcare-associated infections.

7.　　CDC provides healthcare facilities and other partners, such as state health departments, with a range of services, such as analytic tools, national benchmarks and secure access to the NHSN database. Secure access to the NHSN database is generally limited to the healthcare facilities that enter data, to CDC, and, where required by regulation, to CMS;

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however, access for certain purposes, such as outbreak investigations, is provided to state, local, and territorial health departments as well. If other organizations request data access, CDC directs them to contact individual healthcare facilities, which can grant data access privileges to their data as they see fit. While ensuring data security, integrity, and confidentiality, NHSN gives healthcare facilities the ability to see their data in real-time. However, CDC publicly reports aggregate NHSN data on its public websites.

8.   The public can use NHSN data posted publicly on HHS's websites at https://www.cdc.gov/nhsn/datastat/index.html; https://arpsp.cdc.gov/; and https://www.cdc.gov/nhsn/covid19/report-overview.html.

NHSN's Collection of COVID-19 Data

9.   From March through July 15, 2020, NHSN also collected data specifically related to COVID-19 cases from approximately 3,500 of the approximately 6,200 hospitals in the United States on a voluntary basis. CDC created a COVID-19 Patient Impact and Hospital Capacity Module within NHSN and made it available for hospitals to use beginning on March 27, 2020. On March 29, 2020, Vice President Pence notified hospital administrators across the country of the module and requested daily data reports on testing, supplies, capacity, utilization, and patient flows to facilitate the public health response to COVID-19.[1]

10.   On April 10, 2020, HHS Secretary Azar requested that hospital administrators submit hospital capacity data to the Government for the purpose of the emergency response to COVID-19.[2] In a letter, Secretary Azar described several methods through which hospitals

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[1] https://www.whitehouse.gov/briefings-statements/text-letter-vice-president-hospital-administrators/
[2] https://www.hhs.gov/about/news/2020/04/10/coronavirus-pandemic-hhs-letter-to-hospital-administrators.html

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could report these essential data: HHS TeleTracking, NHSN, direct submission of data to HHS, or standardized publication on a state health department's website. The letter explained to hospitals that they could choose any of the submission options, and they only needed to submit data via one mechanism. The data from these various mechanisms are all aggregated in HHS's data management system, known as HHS Protect.

11.   TeleTracking is a commercial product that is used to create HHS TeleTracking, which is now used as HHS's COVID-19 facility hospitalization, utilization, and supply data capture solution.[3]

12.   HHS Protect, which is the largest most flexible secure health surveillance platform within HHS, collects data from various sources, including HHS TeleTracking, NHSN, and hundreds of other sources that provide daily uploads into it. For example, HHS Protect is currently used by the White House Coronavirus Task Force, the National Response Coordination Center, the Federal Emergency Management Agency, the Assistant Secretary for Preparedness and Response ("ASPR"), NORTHCOM, the U.S. Army, the Department of Defense, and CMS. Each of these federal entities, including CDC and ASPR, has access to the aggregated data in HHS Protect.

13.   The HHS Protect ecosystem allows HHS to create a single portal with over 3.5 billion data elements across 200 different data sets in real time to drive HHS's response to the COVID-19 pandemic.

14.   In addition, beginning in late April, NHSN began to collect COVID-19 resident, staffing and supply data from nearly all of the approximately 15,400 CMS-certified nursing homes in the country. All nursing homes are required to report this information to NHSN

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[3] https://teletracking.protect.hhs.gov

pursuant to a CMS Interim Final Rule released on May 8, 2020, 85 Fed. Reg. 27,550 (May 8, 2020), and compliance is currently near 100 percent.

15.   CDC shares NHSN nursing home data with CMS for public, facility-level posting on CMS's webpage at https://data.cms.gov/stories/s/bkwz-xpvg and for use by CMS for the enforcement of reporting requirements. CDC also shares NHSN nursing home data with HHS Protect.

Improved Data Collection Using HHS TeleTracking and HHS Protect

16.   While NHSN received daily data from hospitals, there were challenges with making rapid changes or additions to the system's data elements. In addition, NHSN was not collecting all inventory supply data on a daily basis, as many hospitals do not inventory supplies each day. In order to allow the flexibility that the federal government needed and to obtain the necessary data to inform the distribution of therapeutics and supplies for COVID-19, HHS determined that HHS TeleTracking and HHS Protect were better suited to collect this type of data from all hospitals in the United States. CDC subject-matter experts are able to access to this data and continue their engagement in the analysis, interpretation and action to these data.

17.   The capabilities of NHSN and HHS TeleTracking differ in a number of significant ways. By design, HHS TeleTracking can quickly pivot to capture unique and dynamic data requirements. For example, when HHS sought to collect data on COVID-19 cases for Remdesivir allocations, NHSN required more time to add capacity to a large, multifaceted surveillance system. By contrast, HHS TeleTracking can scale the required data capture framework within 24 hours. In addition, HHS TeleTracking offers modern data collection and dashboarding capabilities that give HHS the ability to collect data rapidly. For example, HHS TeleTracking's set of capabilities established a portal and collected data from 5,800 hospitals in

less than 48 hours. Additionally, with HHS TeleTracking as part of the HHS Protect ecosystem, HHS is able to create new data fields and collect data from 6,200 hospitals in the country in one to three days. The ability to collect data in HHS TeleTracking is expected to improve the automated submission capabilities that are being implemented with certain hospitals and to ease hospitals' data reporting burden by consolidating the reporting portals and easing reporting functionality. Finally, like NHSN, HHS TeleTracking also has the ability to share data daily with HHS Protect.

18.   On July 13, 2020, HHS issued updated guidance designed to streamline hospital reporting. This guidance stated that as of July 15, 2020, all hospitals choosing to submit COVID-19 data should submit it to HHS TeleTracking or to their state health department for submission directly to HHS Protect. The guidance also explained that as of July 15, 2020, hospitals should no longer submit COVID-19 capacity, staffing, and supply-related data to CDC's NHSN.[4] Hospitals that chose to report COVID-19 data to HHS TeleTracking were still required to submit non-COVID-19 data to NHSN as part of their participation in various CMS payment and quality improvement programs.

19.   Though CDC no longer collects COVID-19 hospital capacity and patient impact data directly through NHSN, CDC staff have access to all of this information in HHS Protect. Further, CDC has access to the expanded data sets (to include USA Facts case and death information, U.S. Census data, state and local policy information, and directly reported facility information) found within HHS Protect. Finally, CDC manages access to CDC-provided data in HHS Protect.

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[4] https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf.

20.   While hospital capacity and patient impact data are no longer being collected by CDC through NHSN, the surveillance systems for cases, mortality, nursing homes, studies, and clinical data continue to be led by CDC, including population-based surveillance data on hospitalization through the Coronavirus Disease 2019 (COVID-19)-Associated Hospitalization Surveillance Network ("COVID-NET"), which is a population-based surveillance system that collects data on laboratory-confirmed COVID-19-associated hospitalizations among children and adults through a network of over 250 acute-care hospitals in 14 states.[5] The joint analysis of all of this data will remain within the domain of CDC and the other federal agencies that are part of the COVID-19 response.

21.   States, localities, and tribal partners also have access to the same information on their local situation as the federal government. HHS Protect creates a central repository for this data, allowing more collaboration, flexibility, and access for all federal, state, and local personnel responding to the pandemic.

22.   HHS reports HHS Protect data publicly on HealthData.gov and the HHS Protect Data Hub (https://protect-public.hhs.gov). The HHS Protect Public Data Hub provides high-quality, accessible, and timely information for entrepreneurs, researchers, and policy makers to help drive insights and better health outcomes for all. This site augments Healthdata.gov — the home of HHS open data — with non-government datasets from academia, non-profit organizations, industry, hospitals, and facilities reporting from all 50 states and territories. These data include: COVID-19 reported patient impact and hospital capacity by state; COVID-19 estimated patient impact and hospital capacity by state; COVID-19 state health department

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[5] https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covid-net/purpose-methods.html

reported testing time series; COVID-19 hospital data coverage by facility; and COVID-19 state and county policy orders.

23.   COVID-19 data reporting only became mandatory for hospitals with CMS's issuance of an Interim Final Rule on September 2, 2020. That rule, among other things, requires hospitals "to report information in accordance with a frequency, and in a standardized format, as specified by the Secretary during the [public health emergency] for COVID-19." CMS, Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 85 Fed. Reg. 54,820, 54,822 (Sept. 2, 2020); see 42 C.F.R. §§ 482.42(e), 485.640(d). The current standardized format is specified in an updated version of HHS's guidance that was issued on October 6, 2020.[6]

24.   NHSN continues to collect COVID-19 data from nursing homes and long-term care facilities, leveraging authority from CMS to require reporting from 100 percent of CMS-certified nursing homes across the country.

25.   None of the plaintiffs in this case is required to report any data through NHSN or HHS TeleTracking. None of the plaintiffs has requested or been denied access to either NHSN, HHS Protect, or the HHS TeleTracking portal.

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[6] https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf

I declare under penalty of perjury that the foregoing is true and correct.

Dated: Washington, DC
      November 16, 2020

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PERRYN ASHMORE

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