Chiquita Brooks-LaSure, Administrator  
Centers for Medicare & Medicaid Services, Department of Health and Human Services  
Attention: CMS-1771-P  
P.O. Box 8013  
Baltimore, MD 21244-1850

RE: Medicare Program; Hospital Inpatient Prospective Payment System Proposed Rule for FY 2023 (CMS-1771-P); Changes to Hospital and Critical Access Hospital Conditions of Participation

Dear Administrator Brooks-LaSure:

We appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services’ (CMS) Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule for FY 2023 (CMS-1771-P), particularly regarding changes to hospital and critical access hospital conditions of participation. This proposed rule provides an important opportunity to assess current data reporting systems and processes, address key gaps in data availability and sharing, and reduce administrative burdens associated with reporting related to COVID-19 and potential future public health threats that affect Medicare beneficiaries and the nation’s health care resilience. In our interactions with health care stakeholders, we have found broad support for data reporting requirements that enable local and regional situational awareness and planning, as well as more timely and effective federal support. However, there are also important opportunities for improving transparency and impact of reported data, and reducing burden associated with reporting. The experience with these reporting requirements and other supporting Medicare policies during the COVID-19 pandemic provides an opportunity for CMS, the Centers for Disease Control and Prevention (CDC), the Office of the National Coordinator for Health Information Technology (ONC), and other federal agencies and offices to foster alignment between this rule and other efforts related to advancing health data modernization and interoperability and to support a coordinated response to infectious disease threats across health care, public health, and private sector health care providers. Our comments aim to provide recommendations for how improved clarity and alignment can be achieved. Our comments were prepared with the support of staff from the Robert J. Margolis, MD, Center for Health Policy at Duke University.

ABOUT THE DUKE-MARGOLIS CENTER

Established with a founding gift through the Robert and Lisa Margolis Family Foundation, the Duke-Margolis Center brings together capabilities that generate and analyze evidence across the spectrum of policy to practice, supporting the triple aim of health care—improving the experience of care, the health of populations and reducing the per capita cost. The Duke-Margolis Center’s
activities reflect its broad multidisciplinary capabilities, fueled by Duke University’s entrepreneurial culture. It is a university-wide program with staff and offices in both Durham, North Carolina, and Washington, DC, and collaborates with experts on health care policy and practice from across the country and around the world.

The mission of the Duke-Margolis Center is to improve health and the value of health care through practical, innovative, and evidence-based policy solutions. The Center’s work includes identifying effective delivery and payment reform approaches that support the transition to value-based care and collaborating with expert stakeholders to identify pathways to increase the value of biomedical innovation to patients – both through better health outcomes and lower overall health care spending.

The comments provided on the Hospital IPPS Proposed Rule are informed by the Center’s ongoing work. In May and June 2022, Duke-Margolis hosted two private virtual roundtables of expert stakeholders from across the health care ecosystem, including private payers, health systems, public health experts, federal officials, and state representatives, to discuss key issues and multi-stakeholder opportunities to provide more timely, reliable, and efficient data for COVID-19 and future infectious disease threats. Insights from these discussions informed our comments as well as the enclosed Duke-Margolis issue brief, “Health Care Data Reporting Beyond the Public Health Emergency: Payment Policies to Support Public Health Surveillance and Population Health,” which offers recommendations for how CMS policies and requirements can align with ongoing federal and state initiatives to strengthen public health data infrastructure.

In this document, we discuss:

I. Feedback on aspects of proposed CoP requirements
II. Additional recommendations for CoP requirements and related policies

COMMENTS ON CONDITION OF PARTICIPATION (CoP) REQUIREMENTS FOR HOSPITALS AND CAHs TO REPORT DATA ELEMENTS TO ADDRESS ANY FUTURE PANDEMICS AND EPIDEMICS AS DETERMINED BY THE SECRETARY

I. Feedback on Aspects of Proposed CoP Requirements

A. Reporting mechanisms: We support CoP requirements for timely sharing of key data related to provider experience related to COVID-19, the goal of minimizing reporting burden while maintaining transparency, and the plan to leverage ONC’s national standards and interoperability requirements. However, the proposed rule also notes that “CMS does not intend to supplant or duplicate existing requirements and mechanisms for reporting of public health surveillance data to other federal, state, territorial, local, and tribal agencies.” We recommend that CoP reporting requirements build on emerging federal strategies to encourage use of electronic reporting standards and review opportunities to align existing requirements and mechanisms to reduce duplication and administrative burdens.
associated with existing reporting requirements across a broad range of government agencies. Currently, many health care providers have to report data to multiple separate public health and health care systems, and variation in the definitions of data elements across settings and jurisdictions can lead to both additional effort and inconsistencies. Promoting consistent data reporting approaches could help reduce reporting burden, facilitate bidirectional data exchange using secure and consistent electronic protocols, and improve regional and federal response capabilities. Furthermore, CMS should use these requirements to promote a clear federal communication strategy with reporting entities about how the data is being used, and a “360 degree” data sharing approach that allows contributors to trust that they will receive back timely insights associated with the data they reported for planning and response. For example, CMS CoP requirements and associated payment policies related to data sharing could encourage efficient bidirectional data exchange with state infectious disease and immunization tracking programs. Transparency and clear goals around the key opportunities for data usage can serve as an incentive for efficient, timely, and high-quality data reporting.

B. Data elements: The data elements identified by CMS provide the basis for needed insights to support the quality and safety of health care for providers working to address evolving and potentially very challenging infectious disease threats. As CMS has proposed, required data elements should be based on minimum necessary use and be re-evaluated regularly, in light of the overall cross-agency bidirectional data strategy we have described.

II. Additional Recommendations for CoP Requirements and Related Policies
We recommend that CoP requirements and related policies reflect the following principles. These are described in more detail in the enclosed issue brief.

A. CMS reporting requirements for hospitals and other health care settings, if well designed and focused on quality and safety goals, could have important benefits for beneficiaries, providers, payers, the federal government, and local/state health care preparedness for COVID-19 and future population health threats. Any reporting requirements should be designed to:
   • reduce existing data reporting burdens for CMS and other federal agencies;
   • support reporting needs for state and local public health; and
   • enable health care provider awareness and planning, and local response management.

B. Data elements involved should be based on minimum necessary use, and be re-evaluated regularly to ensure all the data being asked for is being utilized in high-impact ways. While maintaining a “minimum necessary” data collection standard, it is also important to ensure that these data systems do not just monitor
existing public health threats like COVID-19, but can be readily adapted to respond to new threats as they arise.

C. CMS reporting requirements should be linked to clear plans for bidirectional data flow and existing federal strategies for improving data surveillance, including CDC’s Data Modernization Initiative and related interagency efforts.

D. In conjunction with reporting requirements, CMS should build on existing programs, like payments for lab test counseling and related reporting, that provide support for data reporting and actions based on such data to improve the quality and safety of health care for COVID-19 and provide a foundation for better managing other population health threats. The use of these data for quality measures for hospitals, accountable care organizations, and Medicare Advantage plans should be explored.

E. Medicare financial incentives could encourage voluntary regional coordination based on automated reporting of local testing and case data from physician practices, covered pharmacies, and urgent care centers (in addition to hospitals, skilled nursing facilities, and others with required reporting). Such coordination could provide reliable local estimates of infection risk for use in planning care for beneficiaries and further refinement of federal resource and support planning.

CONCLUSION

We appreciate the agency’s attention to the importance of effective data reporting related to COVID-19 and other public health threats. We look forward to further steps by CMS and their federal partners to promote a more efficient, coordinated strategy for timely data sharing and response for current and future public health emergencies. Should CMS or others have any questions about the feedback we provided or wish to discuss how we may be of further assistance, please contact a member of our team (listed below).

Authors from the Duke-Margolis Center:

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Katie Huber, Policy Analyst
Christina Silcox, Digital Health Policy Fellow
Morgan Romine, Chief of Staff (Corresponding author: morgan.romine@duke.edu)
Health Care Data Reporting Beyond the Public Health Emergency: Payment Policies to Support Public Health Surveillance and Population Health

June 17, 2022
Authors

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Acknowledgments

We would like to thank the diverse group of stakeholders who joined our May and June 2022 policy roundtables and participated in informational calls for sharing their expertise; these experts are listed in the appendix. We also thank Patricia Green and Laura Hughes for their communication and design support.

Disclosures

Mark B. McClellan, MD, PhD, is an independent director on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and PrognomIQ; co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network; and receives fees for serving as an advisor for Arsenal Capital Partners, Blackstone Life Sciences, and MITRE.
Background

While SARS-CoV-2 variants continue to evolve with the potential for additional surges in cases, the availability of vaccines and boosters along with rapid testing and effective treatment enables a shift from the current COVID-19 public health emergency (PHE) to sustainable COVID-19 containment. To support and sustain recovery, timely data are needed by health care organizations, including hospitals and health centers, long-term care facilities (LTCFs), and payers, as well as federal, state, and local public health departments to detect and rapidly respond to surges in cases from new variants or declining immunity. The ability of health care and public health organizations to seamlessly share COVID-19 surveillance and case data is critical to preventing serious health impacts, particularly among Medicare beneficiaries and people experiencing high risk of severe COVID-19 illness, as well as for avoiding future economic disruptions. Moreover, similar data may also be needed for responding to seasonal outbreaks as well as future epidemics and pandemics. While such data could be very helpful for health care and public health planning and for preventing adverse outcomes for Medicare beneficiaries and other Americans, any such data collection requirements must also minimize administrative burden and assure transparency in how the data would be used effectively.

Currently, the U.S. public health system lacks a coordinated, national approach to data collection. Fifty state health departments, dozens of territorial and tribal health departments, and thousands of local health departments all have their own reporting requirements. The Centers for Disease Control and Prevention (CDC) is currently investing in additional infrastructure, common standards implementation guided by the Office of the National Coordinator for Health Information Technology (ONC), and tools and resources to support data use by state and local public health, but CDC lacks the authority to require data collection from health care providers or to coordinate consistent and efficient use of such data across the public health reporting ecosystem. Consequently, when the PHE ends, health care organizations may not have the data and situational awareness they need to respond to emerging COVID-19 trends, and the federal government may not be able to provide timely supports to health care organizations facing new threats, placing Medicare and Medicaid beneficiaries as well as other patients at risk.

In September 2020, the Centers for Medicare and Medicaid Services (CMS) issued an interim final rule requiring hospitals and critical access hospitals (CAHs) to report data related to the incidence and impact of COVID-19 to the federal government as a new Condition of Participation (CoP) in Medicare and Medicaid programs during the COVID-19 PHE. The rule also strengthened requirements for LTCFs to report COVID-19 facility data, and laboratories to report COVID-19 test results during the PHE. A December 2020 interim final rule also established additional requirements in the hospital and CAH CoPs for tracking COVID-19 therapeutic inventory and usage as well as tracking the incidence and impact of acute respiratory illnesses during the PHE. These data from health care organizations have been critical to planning, monitoring, and allocating resources during the PHE as well as the country’s broader surveillance of and response to COVID-19. With the potential end of the COVID-19 PHE, CMS regulations related to data reporting need to be updated. A clearer post-PHE strategy is needed to support resource allocation, quality improvement, and patient care, including both efficient data collection requirements and supporting incentives.

CMS payment regulations are a critical part of an efficient and effective strategy for managing COVID-19 and potential future infectious disease threats. CMS has taken additional steps to further update data reporting requirements and incentives for providers participating in Medicare. In particular, the agency recently issued a proposed rule for fiscal year 2023 that would revise the hospital infection prevention and control CoP requirements to require hospitals and CAHs to continue COVID-19 and seasonal influenza reporting after the current PHE through April 2024. It also proposes establishing new reporting requirements that would require hospitals and CAHs to report specific data elements to the CDC’s National Health Safety Network or updated CDC-supported surveillance systems during future PHEs related to epidemics and pandemics. Skilled nursing facilities (SNFs) have also continued to report...
data related to infections, testing, vaccination status, and treatment use. CMS has not yet released its fiscal year 2023 proposed rules for outpatient facilities, physicians, and laboratories.

The transition to post-PHE data reporting with significant payment and policy supports from CMS would play out in the context of a number of new and ongoing federal and state initiatives to strengthen public health data reporting briefly touched on above. In particular, ONC published the Trusted Exchange Framework and Common Agreement (TEFCA) to establish principles for nationwide health information interoperability and create an infrastructure and governance model that would allow health care stakeholders, such as providers, payers, federal and public health agencies, and individual patients, to securely exchange data – including data relevant for public health and local response – across systems and networks. CDC's Data Modernization Initiative is an effort to modernize federal and state public health data and infrastructure to support coordinated data reporting and surveillance of public health threats, building on ONC standards.

ONC and CDC are working together to facilitate public health data interoperability through the development of a “North Star” architecture, enabled by TEFCA, that would use cloud-based technologies to connect federal, state, and local health department information systems while allowing for collaborative governance. One goal of this architecture is to enable coordinated reporting for timely information sharing to support public health activities and health care reporting needs. This architecture aims to allow for multipurpose reporting with appropriate privacy protections; at the state and local levels, some identifiable information may be made available to support patient care and local response efforts such as treatment access and contact tracing, while deidentified data with appropriate privacy constraints would be sent to federal agencies in formats that can be used by CMS and CDC for authorized quality, safety, and public health improvement purposes.

In May-June 2022, the Duke-Margolis Center for Health Policy hosted two virtual roundtables including private payers, health systems, public health experts, federal officials, and state representatives, to discuss key issues and multi-stakeholder solutions to provide more timely, reliable, and efficient data for COVID-19 and future infectious disease threats. Stakeholders discussed challenges and needs associated with COVID-19 and public health reporting as well as opportunities for improved data sharing for public health surveillance. Insights from these discussions are reflected below in our assessment of challenges and opportunities for improved public health reporting and health care response. As this was not a consensus process, findings do not necessarily reflect the views of those participants who contributed their time and expertise to roundtable discussions (a list of participating experts is in the Appendix).

Key Challenges and Needs Related to Public Health Reporting and Surveillance

Across all health care sectors, improved data sharing can enable health care organizations to plan for and contain future COVID-19 risks and other threats to the health of Medicare and Medicaid beneficiaries, and help assure the safe and reliable delivery of health care services for all Americans. While data sharing technology is improving, addressing policies and standards to assure more transparency, practical utility, and bidirectional use of reported data is critical for sustaining necessary data sharing initiatives. Key principles for addressing current challenges include:

• Reducing duplication and administrative burden associated with reporting. Many health care providers have to report the same data, often in slightly different required formats, to multiple public health and health care authorities that are not well connected to each another. Variation in data structures, standards, reporting regulations, and semantic and syntactic definitions across jurisdictions and settings slows the ability to form an evidence-based regional and national picture, contributing to confusion for providers, policymakers, media, and the public. Steps toward
aligning standards for data reporting across jurisdictions could help reduce reporting burden, improve regional response capabilities, and inform providers’ and health plans’ population health efforts. Such steps should reflect diverse state and local capabilities and allow for modification toward greater consistency over time in light of evolving data needs and capabilities.

• Increasing communication, transparency, and utility of reported data. Health care and public health entities value clarity about how the information they report is being used, as well as timely communication and transparency around the resulting aggregate data and analytics to inform their decision making. They also value data flows that connect health care with state and local public health. For example, data exchange including secure “batch” queries helps providers and health plans obtain timely information about vaccination and treatment needs among their patients, informing and improving their population health initiatives. The goal is to promote a “360 degree” data sharing approach that allows contributors to trust that they will receive timely insights associated with the data they reported. Timely access to aggregated regional data is valuable for health system and public health planning, and transparency around such data can serve as an incentive for high-quality data reporting. Regional data should include data from adjacent states and countries where applicable.

• Facilitating alignment and coordination across federal and state data reporting and modernization efforts. Many states have developed innovative and effective solutions to collecting, reporting, and sharing data. Further steps should meet state and local public health authorities where they are while aiming for more efficiencies and standard data reporting approaches when possible, and should encourage consistent reporting on critical data across jurisdictions.

Implications for CMS Regulations Related to COVID-19 Reporting and Response

To accomplish the aims above, CMS policies and requirements should reflect the following principles:

1. CMS reporting requirements for hospitals and other health care settings, if well designed and focused on quality and safety goals, could have important benefits for beneficiaries, providers, payers, the federal government, and local/state health care preparedness for COVID-19 and future population health threats. Any reporting requirements should be designed to:

   • reduce existing data reporting burdens for CMS and other federal agencies;
   • support reporting needs for state and local public health; and
   • enable health care provider awareness and planning, and local response management.

2. Data elements involved should be based on minimum necessary use, and be re-evaluated regularly to ensure all the data being asked for is being utilized in high-impact ways. Examples of such data elements may include:

   • Case reporting, including known and suspected cases, emergency department visits, hospitalizations, and deaths (building off of current reporting requirements)
   • Laboratory results (building off of current requirements)
   • Emergency department visit rates and available hospital bed and intensive care unit (ICU) capacity
   • Linkages to initiatives to improve access to testing, test to treat, vaccines and boosters, and to sustain syndromic surveillance networks including private health care facilities to support health care quality and safety improvements

While maintaining a “minimum necessary” data collection standard, it is also important to ensure that these data systems do not just monitor existing public health threats like COVID-19, but can be readily adapted to respond to new threats as they arise.

3. CMS reporting requirements should be linked to clear plans for bidirectional data flow and federal strategies for improving data surveillance.

   • Any specific data reporting requirements
should be aligned with CDC's Data Modernization Initiative and related interagency efforts, including ONC priority “use cases” for more efficient and reliable data sharing. This approach will help ensure that a coordinated provider data reporting process—increasingly feasible with progress on interoperability standards and secure electronic data infrastructure including cloud capabilities—can meet federal reporting requirements from various agencies, align with state and local requirements, and yield more reliable, robust and actionable data.

- Data use agreements to share required data across agencies and qualified entities should similarly be aligned, with CDC and ONC support for the necessary data infrastructure.
- CMS and/or CDC, as appropriate, should provide regular and timely public reports based on reported data. CMS and other federal agencies should describe the goals of these reports to facilitate feedback and improvement, including how the required data collection is used to improve federal planning and response (e.g., access to tests, treatments, boosters, other supplies in the event of surges).
- CDC should support aligned enhancements in state and local data infrastructure, and supporting tools, to create incentives for state and local governments to align their systems with emerging national standards and best practices for data reporting, exchange, and analysis to support response.

4. In conjunction with reporting requirements, CMS should build on existing programs, like payments for lab test counseling and related reporting, that provide support for data reporting and actions based on such data to improve the quality and safety of health care for COVID-19 and provide a foundation for better managing other population health threats. The use of these data for quality measures for hospitals, accountable care organizations (ACOs), and Medicare Advantage (MA) plans should be explored. These include:

- Health care performance measures on vaccination/boosting rates, with payment incentives for bidirectional exchange with their jurisdiction’s Immunization Information System (IIS) using Fast Healthcare Interoperability Resources (FHIR) standards for secure bulk data sharing. Not all states have IIS rules and capabilities that enable data exchange with health care providers and health plans regarding the immunity status and adverse events involving their patients. However, aligned Medicare provider incentives could provide additional support and momentum for such state IIS modernization efforts.

- CMS could leverage the data reported by hospitals to develop quality measures assessing concepts such as staff vaccination rates and rates of COVID-19 acquired during a stay in a facility. Such measures could be used in programs like the Hospital Inpatient Quality Reporting Program and the Long-Term Care Quality Reporting Program.

The above metrics could be converted to population-based accountability measures in Medicare ACOs and MA plans (e.g., test to treat rates among positive cases and vaccination and booster rates, with race/ethnicity stratification, similar to existing ACO and MA performance measures).

5. Medicare financial incentives could encourage voluntary regional coordination based on automated reporting of local testing and case data from physician practices, covered pharmacies, and urgent care centers (in addition to hospitals, SNFs, and others with required reporting). Such coordination could provide reliable local estimates of infection risk for use in planning care for beneficiaries and further refinement of federal resource and support planning.

Table 1 shows leading “use cases” where CMS regulatory actions could support a more efficient, coordinated strategy for timely data sharing and response for ongoing containment of COVID-19, as well as better situational awareness and response capacity for future infectious disease threats.
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<thead>
<tr>
<th>Population Health Need</th>
<th>Key Health Care Reporting Entities</th>
<th>Key Data Elements</th>
<th>Bidirectional Exchange</th>
<th>Contributions to Timely Aggregate Reports</th>
<th>Supporting Medicare Incentives</th>
<th>Benefits to Medicare and Medicaid patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local/Regional and National Case Trends</td>
<td>• Hospitals and health centers</td>
<td>• Case demographic data</td>
<td>Notification of patient’s primary care provider and health plan to facilitate response</td>
<td>• Local/regional case trends including variants</td>
<td>Continuation of care coordination payments for primary care providers and laboratories that provide timely reporting and counseling</td>
<td>• Better-informed local planning to manage COVID-19</td>
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<td></td>
<td>• SNFs and other congregate care facilities</td>
<td>• Contact information per state/local requirements</td>
<td></td>
<td>• National trends</td>
<td></td>
<td>• Improved federal support for local response</td>
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<td></td>
<td>• Clinical laboratories</td>
<td>• Genotyping of subset of cases to track variant</td>
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<td>• Better, safer care through fewer disruptions to health care organizations</td>
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<td>• Primary care providers</td>
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<td>&quot;Test to Treat&quot; Availability And Use</td>
<td>• Primary care providers</td>
<td>• Case demographic data</td>
<td>Notification of patient’s primary care provider and health plan to coordinate care</td>
<td>• Local/regional trends</td>
<td>Incentive payments for reporting and improvement of timely testing, assessment, referrals, and treatment of eligible patients</td>
<td>Increased access to and use of effective therapies for COVID-19</td>
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<td>• Pharmacy clinics</td>
<td>• Test use</td>
<td></td>
<td>• National trends</td>
<td></td>
<td>Better-informed local resource planning</td>
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<td></td>
<td>• Hospitals and health centers</td>
<td>• Referrals to and use of oral or intravenous treatment</td>
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<td>Improved federal support for local response</td>
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<td>• Long-term care facilities</td>
<td>• Rate of timely treatment in eligible patients per drug emergency</td>
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<td>• State, local, and community-based vaccination sites</td>
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<td>Vaccination and Booster Access and Use</td>
<td>• Primary care providers</td>
<td>• Patient demographic data</td>
<td>Bidirectional bulk data exchange between IISs (as supported by states), primary care providers, and health plans</td>
<td>• Local/ regional trends</td>
<td>Incentive payments for providers to participate timely bidirectional exchange with IIS (as available in state)</td>
<td>Improved access to vaccines and boosters</td>
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<td></td>
<td>• Pharmacies</td>
<td>• Additional patient data per state IIS requirements</td>
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<td>• National trends</td>
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<td>• Emergency department use</td>
<td>Bidirectional exchange with local and state public health entities</td>
<td>• Local/regional trends</td>
<td>Improved planning for surge management</td>
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<td>• Inpatient bed use</td>
<td>• ICU use</td>
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<td>• National trends</td>
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<td>Improved federal support for local response</td>
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<td>Hospital Critical Supplies</td>
<td>Hospitals</td>
<td>• Electronic reporting on critical supply use (N95 masks, PPE, ICU supplies) in PHE</td>
<td>Linkage to and reports from federal/state supply monitoring systems</td>
<td>• Local/regional trends</td>
<td>Improved federal support for local response</td>
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Conclusion

Coordinated efforts to support timely data exchange can facilitate improved surveillance, planning, and response to COVID-19 as well as future infectious disease threats. CMS's fiscal year 2023 proposed rules for Medicare hospitals, outpatient facilities, physicians, and laboratories offer an important opportunity to both update data reporting requirements and offer incentives to encourage timely data reporting and exchange.

Appendix: Meeting Attendees

The views expressed in this issue brief do not necessarily reflect the views of the individuals below nor their organizations.

Ethan Berke, UnitedHealth Group
Kate Berry, AHIP
Bechara Choucair, Kaiser Permanente
Michael Craig, US Centers for Disease Control and Prevention
Angela Dunn, Council of State and Territorial Epidemiologists
Francois Fressin, CVS Health
David Gifford, American Health Care Association
Elizabeth Goodman, AHIP
Tina Grande, Healthcare Leadership Council
Katie Greene, National Academy for State Health Policy
Rajiv Gumpina, Humana
Andres Gutierrez, Family Health Centers of San Diego
Aparna Higgins, Duke-Margolis Center for Health Policy
Katie Huber, Duke-Margolis Center for Health Policy
Dan Jernigan, US Centers for Disease Control and Prevention
Scott Josephs, Cigna
Seth Kroop, US Centers for Disease Control and Prevention
Jen Layden, US Centers for Disease Control and Prevention
Kristi Martin, Centers for Medicare and Medicaid Services
Eva Matthews, Family Health Centers of San Diego
Mark McClellan, Duke-Margolis Center for Health Policy
Deven McGraw, Invitae
Farzad Mostashari, Aledade
Jamie Pina, Association of State and Territorial Health Officials
Greg Poulson, Intermountain Healthcare
Christian Ramers, Family Health Centers of San Diego
Jeff Reczek, US Centers for Disease Control and Prevention
Caitlin Rivers, US Centers for Disease Control and Prevention
Morgan Romine, Duke-Margolis Center for Health Policy
Kenneth Sands, HCA Healthcare
Arjun Srinivasan, US Centers for Disease Control and Prevention
Hemi Tewarson, National Academy for State Health Policy
Micky Tripathi, Office of the National Coordinator for Health Information Technology
Cheryl Walraven, CVS Health
Anne Zink, Alaska Department of Health and Social Services