

## Provisions of the IFC Requiring Additional Guidance from CMS

### Daily Data Reporting as a Condition of Participation

Provision	Issue
<b>Hospital Data Reporting</b>	
Enforcement Process	<p>CMS should provide a detailed description of how the enforcement process will work in instances of noncompliance. For example:</p> <ul style="list-style-type: none"> <li>• How many warning letters will be sent to hospitals not in compliance;</li> <li>• What is the process for coming into compliance after receiving a warning letter.</li> </ul>
Process to challenge CMS warning letter when hospitals can prove they submitted the data to their state or to HHS	<p>In instances where hospitals properly submitted their data directly to HHS or through their respective state, but there was an error in transmission of the data:</p> <ul style="list-style-type: none"> <li>• CMS should provide a detailed process for hospitals to follow to ensure that they are not penalized for an error outside of their control.</li> </ul>
Process for hospitals in situations where they are not at fault for submission, but rather, the state failed to fulfill its obligation.	<p>There is the potential for a situation where a hospital that is required to submit its data to the state does so appropriately, but the state fails to transmit the data to HHS in a timely manner:</p> <ul style="list-style-type: none"> <li>• CMS should provide guidance on how hospitals manage this potential issue.</li> </ul>
Measuring compliance / data completeness	<p>CMS should describe in detail how it will determine whether hospitals have reported complete data. At a minimum, the agency should describe:</p> <ul style="list-style-type: none"> <li>• The data source(s) used</li> <li>• How frequently the agency will pull down data</li> <li>• Data completeness thresholds (with numerator and denominator descriptions)</li> </ul>
Type of data CMS will be looking for and the process for hospitals that do not have COVID-19 patients	<p>CMS should provide a specific list of the different data it will be looking for in order to determine compliance:</p> <ul style="list-style-type: none"> <li>• HHS has not been specific about how it wants hospitals to report in those instances where a hospital does not have any COVID-19 patients for a specific time period.</li> <li>• There is no specific answer to the question: how is that hospital expected to report data.</li> </ul>
Data reporting mechanism, manner, timing and format	<p>To date, hospitals have relied upon ad hoc guidance documents from HHS describing the various reporting mechanisms, deadlines and formats:</p> <ul style="list-style-type: none"> <li>• CMS should provide guidance specifying through what channels hospitals will be informed about reporting formats, definitions and timeframes.</li> </ul>
Identification of a "hospital" for purposes of holding them accountable	<p>CMS usually regulates and pays by CMS Certification Number (CCN). In recent years, as hospitals merged or entered into different agreements, those under the same CCN were regarded as a "hospital" because, we believe, the CCN represents the entity that sought and got permission to care for patients under the Medicare Conditions of Participation:</p> <ul style="list-style-type: none"> <li>• Some hospitals keep their data aggregated and would find it challenging to disaggregate it into campuses.</li> <li>• How will CMS reconcile this in determining what entity is out of compliance?</li> </ul>
Counting reporting of variables	<p>There are different types of variables that are being requested. HHS has identified a relative short list of high priority variables to be reported from among all it is asking for:</p> <ul style="list-style-type: none"> <li>• Additionally, supply data only needs to be reported three times per week.</li> <li>• How will this be factored into the reporting/not reporting determination?</li> </ul>
<b>Lab Data Reporting</b>	
Process for labs in situations where they are not at fault for submission, but rather, the state failed to fulfill its obligation.	<p>To date, HHS has asked for labs to submit their data to state health departments, and in turn, the state health departments submit it to CDC. However, we continue to hear reports that not all states are collecting data at this time:</p> <ul style="list-style-type: none"> <li>• There is the potential for a situation where labs submit data to their states appropriately, but the state fails to transmit the data to CDC/HHS in a timely manner.</li> <li>• Labs should not be held accountable for failures of their state in either data collection or transmission, and we urge CMS to provide guidance to labs on how this issue will be managed.</li> </ul>
Measuring compliance / data completeness	<p>CMS should describe in detail how it will determine whether labs have reported complete data. At a minimum, the agency should describe:</p> <ul style="list-style-type: none"> <li>• The data source(s) used</li> <li>• How frequently the agency will pull down data</li> <li>• Data completeness threshold (with numerator and denominator descriptions) that accounts for required vs optional fields, and the potential for missing data.</li> </ul>
Three-week grace period	<p>The rule itself does not detail what this grace period looks like. The guidance should note this grace period explicitly, and identify a specific compliance date.</p>
Data reporting mechanism, manner, timing and format	<p>To date, hospitals have relied upon ad hoc guidance documents from HHS describing the reporting requirements, as well as technical guidance from the CDC:</p> <ul style="list-style-type: none"> <li>• CMS should specify in guidance the 'source of truth' for details on reporting formats, manner and timing.</li> </ul>
Enforcement Process	<p>CMS should provide a detailed description of how the enforcement process will work in instances of noncompliance. For example:</p> <ul style="list-style-type: none"> <li>• How many warning letters will be sent to labs not in compliance?</li> <li>• What is the process for coming into compliance after receiving a warning letter?</li> </ul>
Process to challenge CMS warning letter when labs can prove they submitted data to their states	<p>In instances where labs properly submitted their data directly to their state, but there was an error in transmission of the data:</p> <ul style="list-style-type: none"> <li>• CMS should provide a detailed process for labs to follow to ensure that they are not penalized for an error outside of their control.</li> </ul>
Data elements	<p>HHS's June 4 guidance was confusing as to whether certain data elements were "required" as opposed to "requested":</p> <ul style="list-style-type: none"> <li>• We would urge the agency not to add any additional data elements to the reporting at this time.</li> </ul>
Reporting data to state of residence	<p>CDC guidance currently calls for labs to report patient's zip code. But the guidance is not clear on whether labs should report data for patients who live outside of the state they're being tested in:</p> <ul style="list-style-type: none"> <li>• Encourage CMS to work with the CDC to clarify this guidance, and encourage CDC to work with states to provide ways of exchanging testing information across states without putting the onus on labs to report to multiple states.</li> </ul>

#### General Comment on the Nursing Home CMP Provisions:

Nursing homes play a critical role in providing a coordinated continuation of care for certain patients. The COVID-19 pandemic has brought to the forefront areas where nursing homes can and should improve to better manage and care for patients during a public health emergency now and in the future. Given that recognition, we understand the purpose behind the enforcement mechanisms for the new nursing home testing requirements, but caution CMS not to use the heavy-handed approach of Civil Monetary Penalties (CMPs) unless absolutely necessary. Rather, providing detailed guidance on how to implement these requirements successfully and offering assistance where needed likely will better prepare nursing homes for compliance as opposed to threatening financial loss. Nursing homes are vital partners for our members and we want to be sure they have the tools, skills and resources necessary to meet the challenges we all are facing.