



## Mercy Direction and Support of UDI on Claims Form:

Mercy Health, Inc., (“Mercy”) through its collaborative partnership with the Healthcare Transformation Group, supports the adoption and use of GS1 Standards. The use of the GS1 single standard improves the efficiency of supply chain transactions, patient safety and recall management.

A core component of the GS1 Standards is the implementation of a single product identifier, referred to as the Global Trade Item Number (“GTIN”). Last year the FDA released regulations that require manufacturers to apply a Unique Device Identifier (UDI) to products. Mercy requires a GTIN be utilized as the UDI and has worked closely with its suppliers to ensure compliance. Mercy’s usage of UDI has shown positive impacts on patient safety, ability to provide outcomes based analysis, monitor recall management, and device surveillance.

Further, the use of a UDI on the billing claims form submitted to payors would allow for a comprehensive dataset. A single UDI, when combined with clinical data, would allow for outcomes based analysis and device surveillance. Providers face significant challenges in tracking outcomes when a patient is provided care across many networks because data is limited to that within their own network. Single use of a UDI allows for a claims data bridge allowing providers to review a complete health record of the care provided to a patient. Mercy supports the use of the UDI on the billing claims form, with the following considerations:

1. The primary purpose of inclusion of the UDI on the claims form is for outcomes based analysis and device surveillance. It is unclear, at this point in the discussions, how this data will be made available to providers. A data rights agreement that has provisions for access should be included.
2. Programmatic changes to provider systems supporting the use and transmission of the UDI on the claims form will required a phased approach. Mercy recommends a three (3) year period for required adoption by providers.
3. The process and system changes required to support UDI on the claims form will require providers to financially invest in infrastructure. Mercy suggests that this cost-benefit analysis provides long term benefits. Information available under the UDI on claims will reduce operational cost and enable providers to drive clinical practice toward the highest quality and lowest cost options.

Mercy is committed to initiatives that improve the quality of care and reduce operational cost. The addition of the UDI on the claims form advances this goal and we support its adoption.

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04/03/2014  
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