570 271 5944 Fax

GEISINGER HEALTH SYSTEM

June 3, 2014

ASC X12 8300 Greensboro Drive Suite 800 McLean VA 22102

Geisinger Direction and Support of UDI on Claims Form:

For many years, Geisinger has been supporting the adoption and use of GS1 Standards through its collaboration and partnership with the Healthcare Transformation Group. Geisinger has demonstrated that the use of a single standard in healthcare can improve patient safety, and the efficiency of supply chain transactions, and recall management.

A core component of the implementation of the GS1 Standards is a single product identifier, the Global Trade Item Number (GTIN). Last year the FDA released regulations that require manufacturers to apply a Unique Device Identifier (UDI) to their products. Geisinger has advocated that the GTIN be utilized as the UDI and has worked closely with its top 20 suppliers to ensure adoption. Currently all top 20 suppliers are either compliant or have plans to be compliant with the standard.

As application of the UDI in healthcare takes hold and suppliers, providers, and industry partners begin to understand its far reaching value around patient safety, outcomes based analysis, recall management, and device surveillance, another important area is gaining industry attention: UDI on the billing claims form submitted to payors. One reason for this attention is that the billing claims form and the data it contains are common among all providers and inclusion of the UDI would provide a comprehensive dataset that could be used for outcomes based analysis and device surveillance - particularly when combined with clinical data from the electronic health record. One of the challenges that all providers experience is tracking outcomes when a patient is provided care across many networks. Most providers are limited to data within their own network and the data for care provided outside of their network are not available. Claims data bridge that gap and allow providers to see all the care activities provided to a patient.

Geisinger supports and will actively advocate for the use of the UDI on the billing claims form but there are some important considerations with respect to that support:

1. The primary purpose of inclusion of the UDI on the claims form is for outcomes based analysis and device surveillance. It's unclear, at this point in the discussions, how this data will be made available to providers and

Geisinger's support is based on the end goal of available access. Part of the process should include a data rights agreement that has provisions for access.

- 2. Programmatic changes to provider systems to support the use and transmission of the UDI on the claims form will take time. We recommend a three year period for required adoption by providers.
- 3. The process and system changes required to support UDI on the claims form will potentially be expensive for providers to adopt. It is our belief that the short term cost of change will be minor compared to long term benefits. The information that will be available will reduce operational cost and enable providers to drive clinical practice toward the highest quality and lowest cost options.

As a provider of health care, Geisinger is committed to initiatives that have the potential to improve the quality of care of those we serve and to lower our operational cost. We see the addition of the UDI on the claims form as such an initiative and we will actively support its adoption in healthcare.

