NUBC Meeting
July 29-30, 2014
American Hospital Association
155 N. Wacker Drive, Suite 400
Chicago, Illinois 60606
TENTATIVE AGENDA
(as of 7/15/14)

July 29, 2014 - Open NUBC Meeting - Davidson Room (A&B)
(Dress: Business Casual)

1:00 - 1:15 pm Welcome and Introductions

1:15 - 1:30 Review and Approve Minutes
- May 21, 2014 Conference Call

1:30 - 3:00 New Business/Other Issues/Changes
- New Condition Code for Initially Implanted (non-replacement) Medical Devices - CMS (Attachment 1)
- Bundling Outpatient Services Rendered within 24 Hours after an Inpatient Discharge on the Inpatient Claim (Attachment 2)
- FL02 - Billing Provider's Designated Pay-to-Address: Reporting/Usage Language (Attachment 3) (also see Attachment 7 - AHIP Statement on Use of Virtual Credit Cards for Claims Payments)

3:00 - 3:15 Break

3:15 - 4:30 Other Issues/Changes - Continued
- Status of Unique Device Identifier
  - New X12 Central Desktop (CD) Workspace (18A - 12N/TGB/WG2 UDI Topic) (Attachment 4)
    - Meeting Schedule Created (1st & 3rd Mondays 3-4:00 pm EST)
    - Shared the UDI Folder from the Billing and Encounter Workspace
  - Proposed Legislation - "Facilitating Participation in Clinical Data Registries Act of 2014''(Attachment 5)
  - FDA and ONC Response to NUCC UDI Letter (FYI - not posted to X12 UDI folder) (Attachment 6)
  - AHIP Statement on Adoption of Unique Device Identifiers in Transactions (Attachment 7)

(OVER)

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Other Issues/Changes - Continued

- Operating Rules - Open Discussion on Industry Experience thus far:
  - Eligibility and Claim Status (effective January 1, 2013)
  - EFT & ERA (effective January 1, 2014)

July 30, 2014 - Open NUBC Meeting - Davidson Room (A&B)
(Dress: Business Casual)

8:00 - 8:30 a.m. Breakfast

8:30 - 10:00 Other Issues:

- DSMO Change Requests #1192, 1193, 1194 (Attachment 8)
- State Issues

NUBC/NUCC Joint Meeting
10:00

- 2015 Meeting Schedule
- Alternative Payment Model
- Unique Device Identifier
- Operating Rules for Claims
- HPID

12:00 - 1:00p.m. Lunch

NUCC Open Meeting - Davidson Room (A&B) (Agenda available from NUCC)
1:00 - 4:30 p.m.

NUBC CHANGE CONTROL REQUEST

(Return to Matt Klischer (matthew.klischer@cms.hhs.gov) x 67488, N2-10-25)

DATE: May 19, 2014

REQUESTOR ORGANIZATION NAME: Centers for Medicare and Medicaid Services

CONTACT PERSON(S): John McInnes, MD, JD

E-MAIL ADDRESS(ES): john.mcinnes@cms.hhs.gov

TELEPHONE NUMBER(S): (410) 786-0791

PERSON(S) WHO WILL PRESENT THE CHANGE TO THE NUBC:
John McInnes, MD, JD, Director, Division of Outpatient Care, Hospital and Ambulatory Policy Group, Center for Medicare, Centers for Medicare & Medicaid Services

DRAFT INSTRUCTION NUMBER (PLEASE ALSO ATTACH DRAFT INSTRUCTION):
See attached draft CR.

DESCRIPTION OF ACTION REQUESTED (e.g. additional occurrence code needed):
Additional condition code needed with suggested language as follows:
Product Placement, Initial−Initial placement of a product in a clinical trial or otherwise

CAUSE FOR CHANGE (regulatory, data collection, other):
A new Medicare payment policy was implemented on January 1, 2014, requiring reporting of value code FD for medical devices furnished without cost to the hospital or when the hospital receives a full or partial credit for the device. However, hospitals must currently use either condition code 49 or 50 along with value code FD. Condition codes 49 and 50 only describe replacement devices. They do not describe no or reduced cost initially implanted (non-replacement) devices, which are not uncommonly supplied to Medicare beneficiaries, especially in the context of medical device clinical trials. Therefore, a new condition code is needed to describe initially implanted medical devices that are no replacement devices.

IMPACT STATEMENT (current form/instruction impacted, funding approved, implementation cost estimate, contractor operations impacted):
Please see the attached 2014 OPPS Final Rule excerpt.

NOTE: Attach any documentation that clarifies this request, including documentation to support a request that is a result of a CMS mandate.

Attachment – One-Time Notification

Pub. 100-20	Transmittal:	Date:	Change Request:

SUBJECT: Implementation of new NUBC Condition Code "XX" "Product Placement, Initial−Initial placement of a product in a clinical trial or otherwise"

Effective Date: April 1, 2015

Implementation Date: April 1, 2015

I. GENERAL INFORMATION

A. Background: Current system edits require a condition code to be billed for outpatient claims when the provider bills Value Code "FD" indicating that they have received a credit on the device. This Change Requests implements the newly created condition code "XX" in order to allow providers to report device credits when the device is an initial placement and not a replacement device.

B. Policy: A new Medicare payment policy was implemented on January 1, 2014, requiring reporting of value code FD for medical devices furnished without cost to the hospital or when the hospital receives a full or partial credit for the device. However, hospitals must currently use either condition code 49 or 50 along with value code FD. Condition codes 49 and 50 only describe replacement devices. They do not describe no or reduced cost initially implanted (non-replacement) devices, which are not uncommonly supplied to Medicare beneficiaries, especially in the context of medical device clinical trials. Therefore, a new condition code is needed to describe initially implanted medical devices that are not replacement devices.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
xxxx.1	CMS shall petition NUBC for a new Condition Code to represent "Product Placement, Initial−Initial placement of a product in a clinical trial or otherwise."										CMS

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
xxxx.2	Medicare Contractors shall accept the new Condition Code.	X					X				CEMA, COBC
xxxx.3	Medicare Contractor shall update system edits to allow Condition Code "XX" in addition to Condition Codes "49" and "50" to be paired with Value Code "FD". XX Initial Product Placement - This is for outpatient claims that have received a device credit upon initial Product Placement. (XX is place holder code for code being requested from NUBC)						X				

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
xxx.4	Provider Education via MLN	X		X							

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	N/A

Section B: For all other recommendations and supporting information, use this space:

N/A

V. CONTACTS

Pre-Implementation Contact(s): For policy questions contact John McInnes at john.mcinnes@cms.hhs.gov.

For institutional claims processing questions contact Fred Rooke at fred.rooke@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *Carriers*:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets

Section B: *For Medicare Administrative Contractors (MACs)*:

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, the hospital is instructed to report as the device charge the difference between its usual charge for the device being implanted and its usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals are instructed to append the ''FC'' modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the ''FB'' and ''FC'' payment adjustment policies (72 FR 66743 through 66749).

2. Policy for CY 2014

In the CY 2014 OPPS/ASC proposed rule (78 FR 43596 through 43597), beginning in CY 2014, we proposed to modify our existing policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy has been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we proposed to reduce OPPS payment, for the applicable APCs listed in Table 17 of the proposed rule, by the full or partial credit a hospital receives for a replaced device. Specifically, under this proposed policy for CY 2014, hospitals would be required to report the amount of the credit in the amount portion for value code ''FD'' (Credit Received from the Manufacturer for a Replaced Medical Device) when the hospital receives a credit for a replaced device listed in Table 18 of the proposed rule that is 50 percent or greater than the cost of the device. Under this proposal, hospitals would no longer be required to append the ''FB'' or ''FC'' modifier when receiving a device at no cost or with a full or partial credit.

In the CY 2014 OPPS/ASC proposed rule (78 FR 43596 through 43597), for CY 2014, we proposed to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which our modified CY 2014 policy applies (71 FR 68072 through 68077). Specifically: (1) All procedures assigned to the selected APCs must involve implantable devices that would be reported if device insertion procedures were performed; (2) the required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and (3) the device offset amount must be significant, which, for purposes of this policy, is defined as exceeding 40 percent of the APC cost. We also proposed to continue to restrict the devices to which the APC payment adjustment would apply to a specific set of costly devices to ensure that the adjustment would not be triggered by the implantation of an inexpensive device whose cost would not constitute a significant proportion of the total payment rate for an APC. We stated that we continue to believe these criteria are appropriate because no cost devices and device credits are likely to be associated with particular cases only when the device must be reported on the claim and is of a type that is implanted and remains in the body when the beneficiary leaves the hospital. We believe that the reduction in payment is appropriate only when the cost of the device is a significant part of the total cost of the APC into which the device cost is packaged, and that the 40-percent threshold is a reasonable definition of a significant cost.

Comment: A majority of commenters supported CMS' proposed adjustment to the OPPS payment for no cost/full credit and partial credit devices, while some commenters requested that CMS rescind its proposal because they believed it would cause additional administrative burden. One commenter argued that using the ''FD'' value code methodology in the OPPS would lead to inaccuracy of claims. One commenter stated that, in some cases, if a full credit were received, the entire APC payment would be consumed by the credit and the hospital would receive no payment for the procedural portion of the service. That commenter suggested that CMS develop a floor for the offset and urged CMS to work with hospital stakeholders to better understand the overall impact to hospitals and to ensure that hospitals would be appropriately paid for the procedural aspect of the device/lead replacement. Another commenter requested that CMS remove APCs 0082, 0083 0104, 0229, 0319, and 0656 from the final listing of APCs covered by the no cost/full credit policy.

Response: We appreciate the support of our proposal by the majority of commenters. We disagree with commenters' assertion that the proposed change from the ''FB''/''FC'' modifiers to the ''FD'' value code for the adjustment to OPPS payment for no cost/full credit and partial credit devices would cause added administrative burden. We believe that the use of the ''FD'' value code will not cause added administrative burden for hospitals. We also disagree with the assertion that using the ''FD'' value code methodology in the OPPS would lead to an inaccuracy in claims. We believe that the use of the ''FD'' value code methodology could lead to greater accuracy in our claims data. However, we are sensitive to the commenter's concerns that, in some cases, if a full credit were received, the entire APC payment would be consumed by the credit and the hospital would receive no payment for the nondevice portion of the costs related to the service. Therefore, we are limiting the OPPS payment deduction for the applicable APCs listed below in Table 30 of this final rule with comment period to the total amount of the device offset when the ''FD'' value code appears on a claim. Hospitals would still be required to report the amount of the credit in the amount portion for value code ''FD'' when the hospital receives a credit for a replaced device listed in Table 18 of the proposed rule that is 50 percent or greater than the cost of the device. We continue to believe that APCs 0082, 0083, 0104, 0229, 0319, and 0656 are appropriately identified as APCs to which the no cost/full credit and partial credit device adjustment policy will apply for CY 2014.

After consideration of the public comments we received, we are finalizing our CY 2014 proposal to modify our existing policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. Specifically, we are finalizing our proposal to require hospitals to report the amount of the credit in the amount portion for value code ''FD'' (Credit Received from the Manufacturer for a Replaced Medical Device) when the hospital receives a credit for a replaced device listed in Table 31 of this final rule with comment period that is 50 percent or greater than the cost of the device. We also are finalizing our proposal to limit the OPPS payment deduction for the applicable APCs listed below in Table 30 of this final rule with comment period to the total amount of

the device offset when the ''FD'' value code appears on a claim.

We proposed to update the lists of APCs and devices to which the proposed modified no cost/full credit and partial credit device adjustment policy would apply for CY 2014, consistent with the three criteria discussed earlier in this section, based on the final CY 2012 claims data available for the CY 2014 OPPS/ASC final rule with comment period.

We examined the offset amounts calculated from the CY 2014 final rule data and the clinical characteristics of the final CY 2014 APCs to determine which APCs meet the criteria for CY 2014. Based on the CY 2012 claims data available for this final rule with comment period, we are not making any changes to the proposed lists of APCs and devices to which this modified policy applies.

Table 30 below lists the APCs to which the finalized modified payment adjustment policy for no cost/full credit and partial credit devices applies in CY 2014.

Table 31 below lists the devices to which the finalized modified payment adjustment policy for no cost/full credit and partial credit devices applies in CY 2014.

BILLING CODE 4120–01–P

Bundling Outpatient Services Rendered within 24 Hours after an Inpatient Discharge on the Inpatient Claim

Issue:
Some payers are apparently requiring hospitals to include outpatient services rendered within 24 hours after an inpatient discharge on the inpatient claim. The following instruction is from one of the health plans Participating Hospital Agreement manual:

> "Services that are provided in the outpatient department within 24 hours prior to, within 24 hours after or during an inpatient admission are paid as part of the inpatient admission. **Only one bill should be submitted with an admission date that is the same as the date the patient was admitted as an inpatient.** The outpatient service will only be considered part of the inpatient admission if there is a similar diagnosis/condition for each. Otherwise, the outpatient service is paid separately."

Some vendors' software does not allow charges to be posted to a patient visit with a service date after the discharge date. They are also concerned about this requirement as it relates to the Type of Bill Frequency Code "1" (Admit through Discharge Claim) as well as the "Through" date in the Statement Covers Period field.

Discussion Notes and Comments:

- This appears to be a bundling experiment based on an episode of care.
- Rolling outpatient services into the inpatient claim is not unusual. Note the 72-hour Medicare window and the common practice of combining ED charges on the inpatient claim for patients directly admitted from the ED.
    - Thus, outpatient charges prior to admission are common; but this is a new requirement that will require systems retooling.
- Concerns about the possibility of varying approaches to this type of episodic bundling.
- Potential implications for secondary claims.
- Under this scenario, the bundled inpatient bill would indicate:
    - A from/through date from the beginning of the episode to the end of the episode.
    - Like other inpatient bills, the admit date is independent and can be sometime after the "from" date. (Adherence to the UB rules regarding the from/through field versus the admit date field is essential in order to do this correctly.)
    - The discharge date will be the "through" date for all services. (Note: Occurrence Code 42 - "Date of Discharge" can be used only when "through" date in Form Locator 06 is not the actual discharge date and the frequency code in Form Locator 04 is that of a final bill (i.e., 1, 4 or 7).
    - The HCPCS on a subsequent (within 24 hours) inpatient related outpatient claim will have to be converted to ICD procedure codes (as is done for direct transfers from ED to inpatient).

Type of Bill Frequency Code 1 - Admit through Discharge Claim

- The definition indicates "… for confined treatment or inpatient period. This will include bills representing a total confinement or course of treatment, and bills that represent an entire benefit period of the primary third party payer."
- The general understanding is that "1" means from the start of treatment through discharge. Note that "Admit through Discharge" may not be 100% technically precise (perhaps "from" would be better than "admit").
    - This is something the NUBC has noted in the past but didn't see a need to revise given that "1" is understood and regularly used on virtually all TOBs including hospital outpatient bills. (For 013x bills "Admit" is a misnomer since there is no inpatient admission and no date is reported).

Questions:

- Is a minor revision to the narrative of TOB Frequency Code "1" recommended?
- Is it really necessary for the provider to do the bundling?
    - Couldn't the health plan's system internally bundle or not bundle the OP claim for payment based on the diagnosis codes? This way billing practices remain consistent; there would be 2 bills (one IP and one OP) regardless of whether the 24 hour post discharge OP service is directly related to the condition for the inpatient hospitalization.
    - However, if the provider does the bundling it might be easier to track outstanding accounts receivable since only a single payment will be expected.

Attachment 3, Page 1 of 1
FOR DISCUSSION PURPOSES ONLY

Effective Date: March 1, 2007 **Form Locator 02**
Meeting Date:

Data Element **Billing Provider's Designated Pay-to Address**

Definition: The address that the provider submitting the bill intends payment to be sent if different than FL 01.

Reporting
• UB-04: Situational. Required when the address for payment is different than that of the Billing Provider in Form Locator 01.
• 005010: Situational. Required when the address for payment is different than that of the Billing Provider. (Note: The purpose of Loop ID-2010AB has changed from previous versions. Loop ID-2010AB only contains address information when different from the Billing Provider Address. There are no applicable identifiers for Pay-To Address information.)

Field Attributes
1 Field
4 Lines
25 Positions
Alphanumeric
Left-justified

Notes
Enter the information provided in Form Locator 02 on the appropriate line:

Line 1 - Pay-to Name
Line 2 - Street Address or Post Office Box
Line 3 - City (Positions 1-16, Left-justified), State (Positions 18-19), and ZIP Code (Positions 21-25)
Line 4 - NOT USED. Reserved for Assignment by the NUBC

Address may include post office box or street name and number, city, state and ZIP Code. Form Locator 02 uses a 5-digit ZIP Code.

External code source for state abbreviations and ZIP Codes:
National ZIP Code and Post Office Directory, Publication 65
The USPS Domestic Mail Manual
Available from:
U.S Postal Service
Washington, DC 20260

Subject: [x12ntgbwg2] Unique Device Identifier (CR 1308) Announcement

From: Laurie Burckhardt via Central Desktop [mailto:reply.32291988.340753.g@in.centraldesktop.com]
Sent: Tuesday, June 24, 2014 7:12 AM
To: Omundson, Todd
Subject: [x12ntgbwg2] Unique Device Identifier (CR 1308) Announcement

ASC X12 Members and Health Care Industry Stakeholders,

In June 2014, ASC X12N/TGB-Business Task Group discussed change request (CR#1308) specific to the reporting of Unique Device Identifier (UDI) in ASC X12 transactions.

ASC X12N leadership has received a significant amount of feedback already indicating that many stakeholders who are new to the ASC X12N process plan to participate in the discussion and requirements gathering related to this CR. With that in mind, ASC X12N has developed a new central desktop (CD) workspace to allow both ASC X12N members and nonmembers to participate in the gathering of business requirements for this change request.

Anyone interested in participating in the development of the business requirements, must send an email to info@disa.organd request to be added to the CD Workspace, 18A – X12N/TGB/WG2 UDI Topic.

The ASC X12N/TGB/WG2 members will begin discussion on CR1308 after the industry has had an opportunity to request access to the cd workspace, and facilitators for this change request have an opportunity to talk and announce dates & times for discussions to occur.

We look forward to working with many valued ASC X12 members and other partners and to forging new partnerships as ASC X12 continues to provide collaboration and innovation to ensure the emerging requirements of health care industry are met.

Sincerely,
Margaret Weiker
ASC X12N (Insurance) Chair

[DISCUSSION DRAFT]

113TH CONGRESS
2D SESSION

H. R. _____

To require the issuance of guidance on the application of the Federal policy for the protection of human subjects with respect to clinical data registries, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. PASCRELL introduced the following bill; which was referred to the Committee on _____

A BILL

To require the issuance of guidance on the application of the Federal policy for the protection of human subjects with respect to clinical data registries, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Facilitating Participation in Clinical Data Registries Act of 2014".

SEC. 2. GUIDANCE ON APPLICATION OF COMMON RULE TO CLINICAL DATA REGISTRIES.

Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services, through the Office for Human Research Protections of the Department of Health and Human Services, shall issue guidance on the application with respect to clinical data registries of the provisions of [subpart A of] part 46 of title 45, Code of Federal Regulations, or equivalent Federal regulations for the protection of human subjects in research.

SEC. 3. UNIQUE DEVICE IDENTIFIER FOR CLASS III MEDICAL DEVICES REQUIRED ON MEDICARE CLAIMS.

(a) IN GENERAL.—Not later than three years after the date of the enactment of this Act, the Secretary of Health and Human Services shall take such measures as are necessary to ensure that, in the case of a class III medical device for which a unique device identifier is required pursuant to section 519(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(f)), not later than four years after such identifier is required to be included on labels or packages for such device, claims for reimbursement under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) for such device include such unique device identifier.

(b) CLASS III MEDICAL DEVICE DEFINED.—For purposes of subsection (a), the term ''class III medical device'' means a medical device that has been approved as a class III medical device pursuant to a premarket approval application under the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

Office of the National Coordinator
for Health Information Technology
Washington, D.C. 20201

Nancy W. Spector
Chair, National Uniform Claim Committee (NUCC)
Director, Electronic Medical Systems
American Medical Association
25 Massachusetts Avenue, NW
Washington, DC 20001

Dear Ms. Spector:

Thank you for your letter in which you express concerns about reporting Unique Device Identifiers (UDIs) in health care claims transactions and the potential burdens and costs that such a requirement might impose on the health care community.

As you are aware, over the last several years, the Food and Drug Administration (FDA) has undertaken an unprecedented effort to develop a multi-stakeholder international consensus on UDIs and the UDI system, leading to the issuance of the UDI final rule in September 2013. At its most basic, the rule requires device labelers (most commonly device manufacturers) to label their device with UDIs and submit device identification information to the FDA-administered Global Unique Device Identification Database (GUDID)—information that will be made publicly accessible for the benefit of all parties. We believe that the fully-realized benefit of UDIs, however, will come through incorporation of UDIs into health information technology, such as electronic health records (EHRs), registries, and claims data sources. In that regard, FDA continues to collaborate with the Office of the National Coordinator for Health Information Technology (ONC) to explore the best ways in which EHR technology could be leveraged when it comes to the UDI. In February 2014, ONC proposed an EHR certification criterion related to the ability of EHR technology to maintain a list of the implantable device(s) patients may have. This proposal was a first step toward expressing the important role EHRs can play in support of the broad adoption and use of UDIs.

A UDI system will enhance postmarket surveillance activities by providing a standard and unambiguous way to document device use in various health IT sources. This information can then potentially be used for assessing the benefits and risks of medical devices. Indeed, FDA's Sentinel Initiative focuses on querying administrative and claims data, maintained by partner organizations, to evaluate the benefits and risks of marketed drugs and biologics. Unfortunately, the data currently lack manufacturer or brand-specific device identifiers and therefore cannot be fully leveraged to perform meaningful medical device postmarket surveillance.

Our report entitled *Strengthening Our National System for Medical Device Postmarket Surveillance*, outlines four key steps—one being to establish a UDI system and promote its incorporation into health IT. This national effort aims to leverage multiple health IT sources, since one alone is not sufficient to adequately address the complexity and heterogeneity of devices and their use. Because of this, we are working with other stakeholders to capture UDIs in registries and EHRs to complement our other postmarket tools. All present unique and long-term challenges.

Although the implementation of a UDI system is vital to advancing device postmarket surveillance, the benefits of widespread adoption of such a system could potentially go far beyond this, to facilitating the access to new treatments, providing a foundation for a global, secure device supply chain, helping to address counterfeiting and diversion, and preparing for medical emergencies. In the end, our goal is simply to work with stakeholders on multiple fronts by using the vast amounts of untapped EHI to realize all these promised benefits, ultimately advancing the nation's public health. In doing so, we certainly recognize the challenges that we and other stakeholders face.

FDA and ONC remain committed to continuing our longstanding practice of ongoing open dialogue and cooperation with all affected parties to ensure that the implementation of the UDI rule by the medical device industry and the incorporation of UDI into health IT by other stakeholders is appropriate and reasonable. We would welcome the opportunity to work with NUCC. If you would like to speak with us to continue the dialogue, please contact FDA's Associate Director of Informatics Anita Rayner (301-796-6002, anita.rayner@fda.hhs.gov) and ONC's Chief of Staff Joshua Brammer (202-205-8094, joshua.brammer@hhs.gov). We hope the members of NUCC will actively join us in that dialogue and in forging a sustainable path to improvements in public health for the American people.

Sincerely,

Karen B. DeSalvo, M.D., M.P.H., M.Sc.
National Coordinator for Health
Information Technology

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

NCVHS Standards Subcommittee
Hearing on HIPAA and ACA Administrative Simplification

Statement of Jeanette Thornton
Vice President, Health IT Strategies
America's Health Insurance Plans
July 14, 2014

On June 10, 2014, the National Committee of Vital and Health Statistics (NCVHS) Standards Subcommittee held a hearing on the current status of various administrative simplification topics. America's Health Insurance Plans (AHIP) appreciates the opportunity to submit testimony for the record in order to provide additional input on two important issues discussed at the hearing: use of virtual credit cards for claims payments and adoption of a Unique Device Identifier (UDI) in administrative transactions.

At the June 10th Subcommittee hearing, testifiers and panel discussions focused on understanding the current state, benefits, and concerns related to both the use of virtual credit cards for claims payments to providers and the use of UDI in administrative transactions. The virtual credit card session focused on increasing trends in use of this electronic payment form and shed light on provider concerns related to enrolling in and processing virtual credit card payments. The central question being debated among testifiers and in the panel discussion is whether use of virtual credit cards support administrative simplification. We understand the Subcommittee's deliberations is focused on whether they constitute a valid transaction and, if so, how to improve their implementation.

With respect to UDI, testifiers consistently agreed to the importance of including UDI in transactions to improve outcomes by monitoring utilization, performance, and safety, supporting more efficient recall, driving quality of care, and managing costs. However, the Subcommittee was left with the outstanding question of where and how to include UDI in transactions.

Below is AHIP feedback on some of the key questions raised at this hearing for consideration by the Subcommittee as it further considers these topics.

Use of Virtual Credit Cards for Claims Payments

AHIP and its member health plans support the use of virtual credit cards as a viable alternative electronic payment channel so long as the conditions of adopting this payment method, including additional fees and payment arrangements, are transparent to providers up front. There are many reasons why a provider may choose not to participate in payments via electronic funds transfer (EFT CCD+ via ACH) and virtual credit cards may provide another payment channel that is faster and more efficient than paper check payments. For health plans, virtual credit cards may

offer a reasonable alternative when providers choose not to enroll in electronic payments via ACH direct deposit. Adopting an electronic payment method should introduce efficiencies, added security, and savings. Virtual credit cards may accomplish this, primarily as an alternative to paper payments when a provider chooses not to enroll in EFT.

As NCVHS considers recommendations to the HHS Secretary regarding the use of virtual credit cards, we recommend you consider the following **best practices** currently used by many health plans and encourage their widespread adoption by other health plans as an alternative payment option:

- Enhancing and strengthening efforts to enroll providers in EFT (CCD+ via ACH) payments (e.g., marketing to providers for EFT, using CAQH CORE's EFT registration process, etc.) as the preferred payment method.
- Offering providers who do not sign up for EFT (CCD+ via ACH) the option of a virtual credit card as an alternative electronic payment method that may to provide a faster payment channel than processing paper payments.
- Educating providers about payment options and including a voluntary ("opt-in") virtual credit card payment method, meaning that a provider could choose to adopt such a payment method, but not be required to do so. "Opt Out" practices and processes that forcefully a provider into virtual credit card payment should not be allowed.
- Switching from standard EFT (CCD+ via ACH) to virtual credit card should not be allowed unless the provider agrees to receive payments by this method and has been given full disclosure of costs, fees, and fee arrangements.
- Adopting operating rules to ensure that when the provider explicitly agrees to the virtual credit card method, that all applicable costs, fees, and fee arrangements between credit card companies and payer, or other third parties have been disclosed and acknowledged.

We encourage NCVHS to take into account that, while health plans are mandated to provide EFT and therefore must invest time and resources to do so, providers are not required to use EFT. This misalignment between health plan and provider requirements means that there is no assurance health plans can fully realize the benefit of their investment in EFT. As a result, health plans should be allowed to look for alternative cost-effective business practices. If a provide chooses not to use EFT, virtual credit cards should be permitted as an efficient and secure option for electronic payment and should not be prohibited because of fees associated with their use. As noted above fees and other considerations associated with use of virtual credit cards should be fully transparent to providers and providers still have a choice to use EFT. However, in working to attain administrative simplification and reducing administrative costs, providers should be part of the solution rather than the full burden falling to health plans.

We strongly encourage NCVHS and standards organizations to further explore the use of virtual credit cards as a payment alternative and we support additional efforts to improve and clarify their adoption and use. We recommend that use cases be developed to highlight the appropriate use of virtual credit cards, especially practices of enrolling providers, to ensure that best practices like those discussed above are more widely adopted by health plans and vendors. Looking to the future, we recommend incorporating virtual credit cards as a valid option in the 835 Health Care Claim Payment and Remittance Advice transaction and that the above best practices be

considered in developing and adopting changes to the 835 transaction standard and operating rules, and that they be in place before the 835 is modified and placed into production.

Adoption of Unique Device Identifiers in Transactions

AHIP and its member health plans have long supported the FDA's efforts to establish a unique device identification system as a critical tool for post-market device surveillance. Health plans' support of and participation in the FDA's Mini-Sentinel project have resulted in the successful investigation of safety concerns related to drugs. Inclusion of UDI information will allow the expansion of the Mini-Sentinel's project to support FDA's need for safety and outcomes information related to medical devices.

We agree that there is value in including UDIs in health claims transactions to improve quality and lower costs. Health plans use administrative claims information to evaluate patterns of care, identify missed opportunities, assess effectiveness, and monitor long-term product safety. Given health plans' ability to aggregate administrative claims data and analyze trends using this data, much could be learned about the safety and effectiveness of particular devices with inclusion of UDI information. Used in conjunction with comparative effectiveness research, UDIs in claims could contribute to the development of value-based insurance design and value-based payment models.

As NCVHS continues its work in this area, we offer the following recommendations to optimize the use of UDI information:

- Early recommendations from various stakeholders have indicated that incorporating UDI information into the body of the claims transactions may be more valuable than reporting it in the claim attachment, given the lack of standardization and inconsistent use of the claim attachment at this time. However, we feel it may be premature to define the long-term direction regarding which transaction (or transactions) in which to report a UDI in the future. NCVHS, WEDI, and Standard Development Organizations should continue to engage key industry stakeholders in reaching a final recommendation.
- As an interim step, the UDI information could be voluntarily incorporated into the claims transaction with a situational rule to enable interested providers and health plans, on a voluntary basis, to transmit and use UDI information.
- Further consideration should be given to whether there are particular devices for which it would be most beneficial and appropriate for UDI inclusion in claims. We recommend starting with high-risk implantable devices.
- Additional thought should be given to the location, security, and length of time related to storage of the UDI information specific to individual health plan members.
- Parallel efforts should be encouraged by NCVHS and other stakeholders to develop processes to support providers' efforts to incorporate UDIs into *clinical data sources,* such as registries and electronic health records (EHRs). Inclusion of UDI's in EHRs places critical information at the site of care and in the hands of providers who can most effectively identify patients affected by product recalls and other safety issues in real time. Inclusion of UDIs in clinical data sources also gives providers access to the information necessary to help inform selection of interventions, reduce errors, and

improve overall quality of care. Finally, inclusion of UDIs in clinical data sources enhances the capability for longitudinal studies that transcend payer billing systems.

We agree with the Subcommittee on the importance of these two topics and look forward to additional discussions and potential recommendations on the use of virtual credit cards and UDIs to further support administrative simplification.

We thank the Subcommittee for the opportunity to submit this testimony for the record.

DSMO CRS #1192

#	Submitter Information	Type of Request	Business Reason	Suggestion	Status and Due Date	
1192	Date 4/9/14 Claudette Sikora (cms.hhs.gov)	Professional Claim (HCFA 1500)	CMS is seeking a change to the HIPAA standard for the ASC X12 837 professional claim transaction in order to process Medicare subrogation claims. In accordance with 42 U.S.C. § 1395u(b)(6)(B); and 42 C.F.R. 424.66, Medicare is required to pay Part B claims under an Indirect Payment Procedure (IPP) to qualifying entities under qualifying conditions. In this IPP, the entity seeking payment has provided a complementary health benefit plan to a Medicare beneficiary and has paid a Medicare provider for the services the beneficiary has received. Medicare is required to reimburse the IPP (when certain qualifications are met). Currently Medicare is processing these claims via paper. While the current volume of paper IPP claims is manageable, we anticipate more complementary health plans to become registered to submit IPP claims, and the volume of IPP claims to increase significantly over time. Therefore, CMS would like to establish a process for submitting these claims electronically as soon as possible; however, the 2010AC loop usage is restricted to Medicaid subrogation.	A possible way to accommodate this business need is to change loop 2010AC (Pay-to Plan Name Loop) such that it can accommodate subrogation claims other than Medicaid. The current requirement that "this loop may be used only when BHT06=31" appear to mean that it can apply only to Medicaid subrogation claims. The definition of code 31 is "Subrogation Demand The subrogation demand code is only for use by state Medicaid agencies performing post payment recovery claiming with willing trading partners..."; we are open to suggestions, however.	90 day review Due: 8/19/14	

DSMO CRS #1193

#	Submitter Information	Type of Request	Business Reason	Suggestion	Status and Due Date	
1193	Date 4/10/14 Jill Money (bcbsm.com)	Professional Claim (HCFA 1500)	Request for changing Situational Rule in 005010X222 (Professional 837) TR3 for LIN segment. This request pertains to specialty drugs and specialty drug providers whose scope of practice allows them to provide/administer drugs that are billed to the medical benefit such as individual practitioners (md, do, cnp, physician assistants), vaccine immunization pharmacies, home infusion therapy, ambulatory infusion center, specialty pharmacies, durable medical equipment, and hemophilia. In order to remain competitive and to best service its members, it is imperative that commercial payers be able to develop and implement comprehensive specialty pharmaceutical programs that are in accordance and compliance with the standard transaction rules. Over the last 5 years, specialty pharmacy has become one of the fastest growing areas in healthcare, with a growth rate of 15% - 20%. The medical-drug spend on specialty drugs is increasing 10% - 13%, which is 2-3 times faster than pharmacy drug costs. Both cost and utilization trends are dramatically increasing for specialty drugs; 20% of specialty drug costs could comprise up to 50% of the total drug spend for some commercial payers by 2015 if not managed appropriately. Employer groups are requesting utilization and cost management of specialty drugs from commercial payers. They need to have programs in place to respond to these requests. Specialty/high cost drugs are currently not managed under the medical benefit due to situational rule limitations for commercial payers resulting in the inability to capture and price medical drug at the NDC level data and inconsistent pricing of Not Otherwise Classified Drug Codes (NOC)	Revise the situational rule for Loop 2410, LIN Segment Current Language: Required when government regulation mandates that prescribed drugs and biologics are reported with NDC numbers. OR Required when the provider or submitter chooses to report NDC numbers to enhance the claim reporting or adjudication processes. If not required by this implementation guide, do not send. Proposed Changed Language: Situational Rule Required when government regulation mandates that prescribed drugs and biologics are reported with NDC numbers OR Required when the provider or submitter chooses to report NDC numbers to enhance the claim reporting or adjudication processes. OR Required when an HHS approved pilot project specifies	90 day review Due: 8/19/14	

			The ability to address market trends by managing specialty drugs under the medical benefit will: • Ensure the appropriateness and use of high-cost and disease-specific medications/drugs • Allow commercial payers to follow the same rules and standards currently only available under federal and/or state mandated programs such as Medicare and Medicaid for industry standards of managing specialty drugs in the marketplace • Address claims systems pricing and processing capabilities (reduce manual processing and duplicative efforts) • Optimize the quality, consistency, cost and utilization management controls • Optimize the use of specialty drugs in other distribution channels • Provide membership and groups with accurate pricing and application of clinical criteria. • Manage the high costs associated with specialty pharmaceuticals and reduce exposure to uncontrolled costs. • Capture the NDC level of information to enhance reporting and pricing to capitalize on discount rates. • Provide clinical criteria to providers before treatment begins. • Allow for optimal rebate management and outcomes based contracting. For version 005010, an inconsistency exists in instructions for using the claim level AMT segment when reporting secondary payments. Section 1.10.2.13, page 39, states, "Report the claim coverage amount or service allowed amount in the claim level AMT segment using qualifier AU (claim level) or B6 (service level) in AMT01." However, no qualifier value B6 is listed for the claim level AMT segment at position number 620, pages 182-183. Also note that the examples in section 3.3, starting on page 232, use an AMT01 qualifier value of AU for service line adjustments; however, no qualifier value of AU is listed for the service line level AMT segment at position number 1100, pages 211-212.	reporting of Universal Product Number (UPN) by parties registered in the pilot and their trading partners. OR Required when government regulation mandates that medical and surgical supplies are reported with UPN's OR Required when adjudication is impacted by the inclusion of specific NDC numbers for biological and specialty drugs. If not required by this implementation guide, do not send		

DSMO CRS #1194

#	Submitter Information	Type of Request	Business Reason	Suggestion	Status and Due Date	
1194	Date 4/18/14 Holly George (capario.com)	Professional Claim (HCFA 1500)	As I understand it, as part of the Affordable Care Act, CMS has established a requirement for Health Maintenance Organizations offering Medicare programs (Medicare Advantage - MA) to report the patient coinsurance, co-pay and deductible information. This requirement is to establish a mandatory maximum out-of-pocket (MOOP) limit on overall cost-sharing for Parts A and B services. In order to effectively gather and report this information to CMS, the Health Maintenance Organizations are requiring their contracted Independent Physician Associations to submit their professional encounter claims, which are for reporting purposes only, with the coinsurance, co-pay and deductible amounts. In the 5010 837P transaction, the only way this data can be reported is in a secondary claim. Billing an encounter claim as secondary is burdensome and there should be a method to report this data on a primary claim if it is now being required.	In the next version of the X12 837P (and perhaps the X12 837I as well). Create segments to report this data on a primary claim.	90 day review Due: 8/19/14	