DSMO **Designated Standards Maintenance Organizations**

Annual Report

TO

NCVHS **National Committee on Vital and Health Statistics**

June 2013

For the period January 2012 through December 2012

The Designated Standards Maintenance Organizations continued a normal working schedule since the previous report dated March 2012.

The following totals are for the time period of January 2012 through December 2012:

14 Number of change requests entered
2 Withdrawn by submitter
1 Withdrawn by administrator
11 Total number completed through the process

Table 1 – Number of Change Requests Reviewed by Monthly Batch

January 2012	0	June 2012	0	November 2012	2
February 2012	1	July 2012	1	December 2012	2
March 2012	1	August 2012	1		
April 2012	1	September 2012	2		
May 2012	0	October 2012	3	**Total**	**14**

Table 2 – Overview of Change Requests by Report Period

	7/01-4/02 10 Months	5/02-6/03 14 Months	7/03-10/04 16 Months	11/04-9/05 11 Months	10/05-11/06 14 Months	12/06-2/08 15 Months	3/08-10/09 20 Months	11/09-12/10 14 Months	1/11-12/11 12 Months	1/12-12/12 12 Months
Total Submitted	**143**	**159**	**67**	**17**	**27**	**13**	**12**	**21**	**40**	**14**
Monthly Average	14.3	11.4	4.2	1.5	1.8	.9	.6	1.5	3.3	1.2
Withdrawn										
Administrator	9	6	17	6	3	0	2	9	1	1
Submitter	52	36	15	2	10	4	6	5	7	2
Total Completed	**82**	**117**	**35**	**9**	**14**	**9**	**11**	**7**	**32**	**11**
Monthly Average	8.2	8.4	2.2	.8	.9	.6	.55	.5	2.6	.9
Appeals										
Withdrawn	1	0	0	0	0	0	0	0	0	0
Upheld	0	3	1	0	0	0	0	0	0	0
Denied	5	7	0	1	0	0	0	0	0	0
Remanded	0	2	0	0	0	0	0	0	0	0

The DSMO representatives originally established eight broad categories, lettered A through H. Since then two new categories have been added and labeled I and J. The meaning of all categories follows:

A **Modifications necessary to permit compliance with the standard/law**
According to DHHS, necessary items include
1. Something in the adopted standard or implementation specification conflicts with the regulation.
2. A non-existent data element or code set is required by the standard. (removal of data content that is not supported by the healthcare industry any longer)
3. A data element or code set that is critical to the industry's business process has been left out.
4. There is a conflict among different adopted standards
5. There is an internal conflict within a standard (implementation guide).

B **Modifications**
Classified as additions or deletions of data elements, internal code list values, segments, loops; changes in usage of segments, data elements, internal code list values; changes in usage notes; changes in repeat counts; changes in formatting notes or explanatory language that do not fall into Category A.

C **Maintenance**
Classified as items that do not impact the implementation of the transaction. Items classified as Maintenance will require no further DSMO actions. Items are to follow the SDO process.

D **No Change**
Classified as items that the implementation guides do meet the needs requested, or did go through the consensus building process originally to meet need. May request follow up by the submitter for further action.

E **DHHS Policy**
Classified as items that require follow up by the Department of Health and Human Services in regards to the Final Rule.

F **Withdrawn by Submitter**
Classified as items that have been removed from Change Request System consideration.

G **Appeal**
Classified as items where the DSMOs did not reach consensus on response and will follow the appeal process.

H **Industry Comment Request Process**
Classified as items that require comments from the industry to determine consensus.

I **Recommendation for adoption of new/modified HIPAA standard**
Classified as items that result in the recommendation to the National Committee on Vital and Health Statistics for the adoption of a new/modified HIPAA standard. Examples might include a request for a new transaction, or a new version or release of an already-named standard for a given transaction(s).

J **Out of DSMO Scope**
Classified as items that are not in the scope of the DSMO. An example is change requests for modifications to transactions not named in HIPAA.

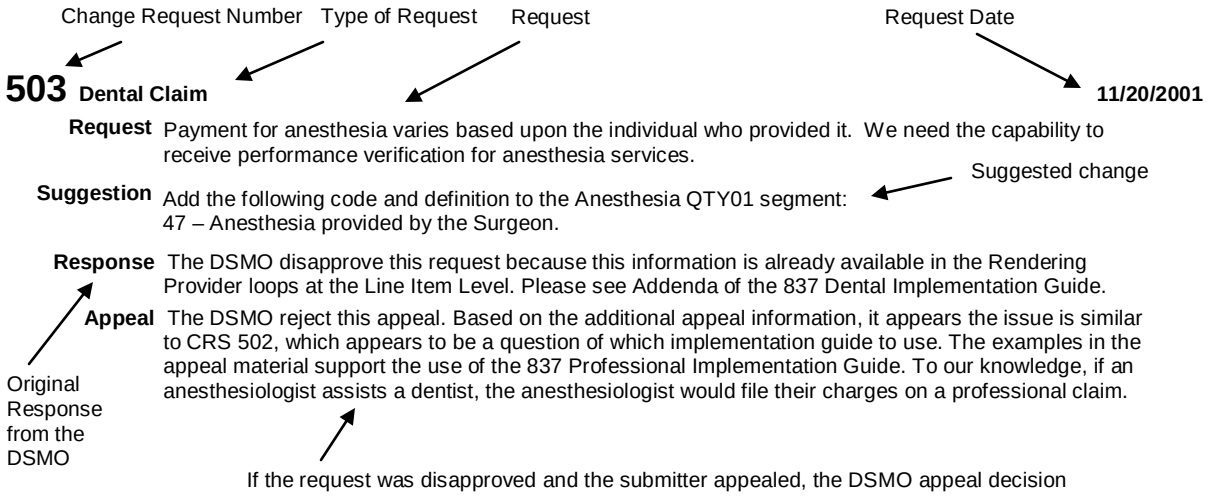
Table 3 – Categories of Change Requests by Report Period

	7/01-4/02 10 Months	5/02-6/03 14 Months	7/03-10/04 16 Months	11/04-9/05 11 Months	10/05-11/06 14 Months	12/06-2/08 15 Months	3/08-10/09 20 Months	11/09-12/10 14 Months	1/11-12/11 12 Months	1/12-12/12 12 Months
Completed	**82**	**117**	**35**	**9**	**14**	**9**	**11**	**7**	**32**	**11**
Totals | Percent by Category										
A	0 | 0	0 | 0	0 | 0	0 | 0	0 | 0	0 | 0	0 | 0	0 | 0	0 | 0	1 | 9
B	31 | 38	57 | 49	12 | 34	5 | 56	0 | 0	0 | 0	2 | 18	1 | 14	10 | 31	2 | 18
C	4 | 5	4 | 3	1 | 3	0 | 0	2 | 14	0 | 0	0 | 0	0 | 0	2 | 5	2 | 18
D	47 | 57	56 | 48	20 | 57	2 | 22	5 | 36	1 | 11	7 | 64	6 | 86	20 | 63	6 | 55
E	0 | 0	0 | 0	1 | 3	0 | 0	0 | 0	0 | 0	0 | 0	0 | 0	0 | 0	0 | 0
I			1 | 3	0 | 0	7 | 50	8 | 89	1 | 1	0 | 0	0 | 0	0 | 0
J				2 | 22	0 | 0	0 | 0	0 | 0	0 | 0	1 | 1	0 | 0

The change requests that have completed the DSMO process for the specified time period are assigned to four of the categories listed above. The following totals are for the **11** completed change requests for this report period:

A 1 change requests assigned to this category
B 2 change requests assigned to this category
C 2 change requests assigned to this category
D 6 change request assigned to this category

The appendix to this document contains details for the **11** change requests that have completed the DSMO process containing the following types of information:



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Category A

Modifications necessary to permit compliance with the standard/law

According to DHHS, necessary items include
1. Something in the adopted standard or implementation specification conflicts with the regulation.
2. A non-existent data element or code set is required by the standard. (removal of data content that is not supported by the healthcare industry any longer)
3. A data element or code set that is critical to the industry's business process has been left out.
4. There is a conflict among different adopted standards
5. There is an internal conflict within a standard (implementation guide).

1182 Retail Pharmacy Claim 11/11/2012

Request The National Council for Prescription Drug Programs (NCPDP) is submitting the following request to allow the enhancement of the NCPDP Telecommunication Standard Implementation Guide Version D.Ø named under HIPAA.
Description of the problem
Government inspectors alleged in a report based on 2009 data found three-quarters of contractors who processed prescriptions for the Medicare Part D program may have wrongly refilled some medications classed as Schedule II controlled substances, which include strong pain killers and other drugs considered at high risk for abuse. Those refills were worth a total of $25 million.

"Paying for such drugs raises public health concerns and may contribute to the diverting of controlled substances and their being resold on the street," said the report by the U.S. Department of Health and Human Services inspector general.

The Centers for Medicare and Medicaid Services said in response to the report that the Inspector General was misinterpreting partial "fills" dispensed to patients in long-term care facilities as refills. Partial fills occur when a pharmacist does not dispense all doses of the prescribed medication at one time. But the report said there was little evidence of that.

The NCPDP Telecommunication Standard Implementation Guide Version D.Ø does not support the OIG's strict interpretation of the use of the Fill Number (4Ø3-D3) field. The Fill Number field is used in the industry to represent the fill number and not necessarily the refill number. NCPDP will work to clarify the definition to avoid further misinterpretation that this represents the refill number.
As such, the following question was submitted by the Centers for Medicare and Medicaid Services Medicare Drug Benefit Group to NCPDP's WG9 Government Programs Medicare Part D FAQ Task Group. This Task Group answers questions that are submitted from industry stakeholders to help with consistent application of Medicare Part D policy where claims or other applicable transactions, Prescription Drug Events (PDE) are involved.

"We need to determine if there is a way to use the standard appropriately to distinguish incremental cycle fills of a controlled substance prescription in LTC claims from illegal refills. Some auditors, looking at the PDE data, are concluding that fill numbers greater than 0 are illegal refills. They believe that these should be indicated as partial fills.

We believe that in long term care pharmacies, where prescribed amounts may be dispensed in multiple increments (i.e., "short cycle dispensing"), the dispensing status field may not be used on an electronic claim to indicate a partial fill in the sense of the term as used in 21 CFR §1306.13(b)1. The use of this field is dictated by the NCPDP (HIPAA) standards and is limited to "situations where inventory shortages do not allow the full quantity to be dispensed"2. Use of a field in contravention of the standard would be a HIPAA violation.

We are not aware of another means of a LTC pharmacy distinguishing multiple partial fills of one controlled substance prescription for billing purposes (to avoid rejection as a duplicate claim) without using the fill number field. We would like to work with the pharmacy industry through NCPDP to determine if there is another acceptable use of the standard that utilizes a different field. If there is, we will explore our options for either encouraging or requiring the use of that alternative process to improve controls over fraud, waste and abuse. In the meantime, we believe use of a fill number greater than "0" on PDEs associated with LTC pharmacy short cycle fills of controlled substances cannot be relied upon to identify illegal refills."

121 C.F.R. § 1306.13(b) allows for the partial filling of prescriptions schedule II controlled substances in order to reduce the quantity of drugs on hand. "(b) A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of the Act. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a

period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication."

2 From version D.Ø Telecommunication Standard Data Dictionary (page 33):
Field: 343-HD
Name of Field: Dispensing Status
Definition of Field: Code indicating the quantity dispensed is a partial fill or the completion of a partial fill. Used only in situations where inventory shortages do not allow the full quantity to be dispensed.

Suggestion Recommendation
NCPDP recommends the solution is to allow the Telecommunication Standard Implementation Guide Version D.Ø to specify the conditional use of field Quantity Prescribed (46Ø-ET) which is currently not in use in the claim billing transaction. During the review and approval of the Telecommunication Standard Implementation Guide Version D.Ø a business case for this field was not brought forward and the situation for the use of the field was designated as "not used" in all billing transactions. Allowing the use of this field will communicate the actual quantity prescribed in the transmission of the claim. The data would be available to validate whether or not there are inappropriate fills in excess of the quantity prescribed.

NCPDP will work with OESS for a timely regulatory notice and notification to the industry.

Response Approved. The DSMO believes the industry will benefit from this improved version of the standard and the expanded business functions it provides.

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Category B

Modifications

Classified as additions or deletions of data elements, internal code list values, segments, loops; changes in usage of segments, data elements, internal code list values; changes in usage notes; changes in repeat counts; changes in formatting notes or explanatory language that do not fall into Category A.

1166 Health Care Eligibility Requests or Responses 3/5/2012

Request Representing dental interests for Transaction 27, the response needs to support the ability to make a lesser allowance toward a submitted service with the difference chargeable to the patient.

Suggestion Add message such as EB"A"********.2*****AD:D2393-MSG*posterior Resin Covered as Almagam

Response Approve. The DSMO approves this request for ASC X12 to define the technical solution in a future version. The DSMO also recommend X12 investigate additional dental data content in the eligibility transaction (270/271).

1175 Institutional Claim (UB-92) 9/12/2012

Request ASC X12 TR3 005010X223 for submitting institutional claims or encounter reports (837i) permits the inclusion of Value Information in multiple HI segments with HInn composite -01 containing a value of "BE". When such segments are present, HInn composite -02 may contain a value that identifies any NUBC code list. Data values from any such NUBC code list are presently only permitted to be stored in HInn composite -05; which is data type R and intended to contain Monetary Amounts. ASC X12 Data type R requires suppression of leading zeroes. Unfortunately, some NUBC code list values contain leading zeroes which are either significant or required by the NUBC coding rules. For example, see NUBC code list 45 for Accident Hour. When NUBC code lists data values with significant leading zeroes are desired to be included, a conflict between the NUBC coding rules and ASC X12 data type R is created.

Suggestion Add language to the description of HInn composite -02 that requires use of HInn composites that are suitable to the type of NUBC code list data values being included in a transaction, and make HInn composites -03, -04, -06, -07, -08, and -09 Situational rather than Not Used. Additionally, make HInn composite -05 Situational rather than Required.

Response Approve. X12 will process the data maintenance required and define the technical solution for inclusion in a future version.

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Category C

Maintenance

Classified as items that do not impact the implementation of the transaction. Items classified as Maintenance will require no further DSMO actions. Items are to follow the SDO process.

1178 Pertaining to more than one, or not sure

9/28/2012

Request Contract Type code value request for Encounters reporting (Post-adjudicated claims)

Transactions:
837 Professional and Dental - 2300/CN101, 2400/CN101
837 Institutional - 2300/CN101

Requesting the use of code value 'FR' (Firm Fixed Price) which is listed in the 837 Standard Workbook for data element CN101, but not in the X12 TR3. Otherwise, the creation of a new code value is needed.

The available values found in the X12 TR3 does not correspond to how majority of our providers are reimbursed. For many providers and outpatient hospital services, the reimbursement is on a fee-for-service fee schedule basis that is derived from relative value units and not based on DRG, per diems, flat rates or percentages.

Current CN101 Contract Type values per the X12 TR3:

01	DRG
02	Per Diem
03	Variable Per Diem
04	Flat
05	Capitated
06	Percent
09	Other

Suggestion Encounters reporting would be able to utilize the data in the Contract Information CN1 segment. An additional code would identify the reimbursement arrangement more appropriately.

Response Approve. X12 will define the technical solution for inclusion in a future version of the Post-adjudicated data reporting 837 guide.

1185 Professional Claim (HCFA 1500)

11/13/2012

Request The 5010 ASC X12 837 Professional TR3 does not support identifying both a locum tenens provider and the provider for whom he/she is substituting services. Medicare needs to identify both on a claim in accordance with Medicare law and because of fraud associated with the faiiure to identify both providers on a claim.

Suggestion Medicare recommends that there be a separate Locum Tenens Provider Loop; allow the Rendering Provider Loop to be for the original provider in a locum tenens situation. Although the TR3 indicates that the locum tenens provider be identified in the Rendering Provider Loop, doing so results in there being no place to identify the original provider for whom the locum tenens provider is substituting. The Billing Provider Loop might work in instances where the billing provider is an individual, but it fails when the billing provider is a group practice, and there is no way to reliably identify the individual for whom the locum tenens provider was substituting.

Response Approved. The DSMO supports the business reason for identifying both providers and recommends that the technical solution be determined by X12.

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Category D

No Change

Classified as items that the implementation guides do meet the needs requested, or did go through the consensus building process originally to meet need. May request follow up by the submitter for further action.

1171 Professional Claim (HCFA 1500) 7/12/2012

Request Massachusetts' office of Health Safety Net (HSN) is requesting a segment/element to be added to the 837 Professional that would allow the Community Health Centers notifying HSN whether the patient's deductible is fully met. This information is needed by HSN for calculating the payment. HSN payment is processed at 80% of what a provider's "full" payment would have been with providers collecting the remaining 20% from the patient and applying it to the patient's deductible, if the deductible was not fully met. Once a patient's deductible has been fully met, HSN payments would be processed at 100%.

Suggestion Use 2300:K301 to submit the information needed.

2300:K301 Poistion 1 - 2 >>>>> State code (i.e. MA)
2300:K301 Poistion 3 - 5 >>>>> Division (i.e. HSN)
2300:K301 Position 6 - 80>>>>> required data (i.e. 100)

The 2 possibilites for MA, HSN is:
K3*MAHSN80~
K3*MAHSN100~

Response Disapprove. Based on the information provided, the DSMO disapprove the request. The requestors need to determine a permanent solution in their systems to capture this information. Provider's cannot be expected to track and report this information to a payer. They have no access to claims processed for other providers, which impact a member's deductible.

1173 Payment of a Health Care Claim 8/3/2012

Request Submitted on behalf of:
Mickey Lourenco
Care New England, Medicare Supervisor
mlourenco@carene.org

The X12 implementation of the 5010A.1 format of an 835 file has created a tremendous issue and burden for our hospital regarding the Bill Summary pages – TS306-TS312 Monetary Amount. Much of the Provider Summary Information loops as in my issue of the 2000.TS3, was removed as "Usage change to Not Used".

So, it was changed from summarizing this information on the Bill Summary pages, by Net Reimbursement (TS309), Cost Outlier information, etc., to not providing this information at all – the fields are now blank.

This is a very important information and we monitor these fields daily, as well as, report this information to the highest levels of our organization. Please consider providing this again.

Response Disapprove. The DSMO recommends that the submitter consider opening a new request that clearly states the business reason for the proposed change, the specific proposed change, and information on how current reports/data supplied fail in providing the requested data.

1174 Professional Claim (HCFA 1500) 8/27/2012

Request Our company is a vision health care organization and utilize the 837 to complete claims transactions. In the vision world we communicate lens prescription information on our claims. Prescription data is the patients eye sight information and not the typical drug prescription. I would like to suggest that we enhance the 837 for vision claims to have a section added for this data or even create a 837-V.

Suggestion Either create a 837-V or modify the 837 to gather Vision Rx data.

Loop ID 2400 Service Line Info – NTE segment. This segment has two elements:

1. NTE01 (Note Reference Code) --> This value should always be: ADD (for additional information).
2. NTE02 (Note Description) --> This is an 80 character alpha/numeric field.

The format for NTE02 would be as follows:

Position	Length	From	To	Description	Value/Format
1	1	1	1	Right Plano	“Y” or “N”
2	1	2	2	Left Plano	“Y” or “N”
3	1	3	3	Right Sphere Sign	“+” or “-“
4	6	4	9	Right Sphere	xxx.xx
10	1	10	10	Right Cylinder Sign	“+” or “-“
11	6	11	16	Right Cylinder	xxx.xx
17	3	17	19	Right Axis	xxx
20	7	20	26	Right Prism	xxxx.xx
27	1	27	27	Right Base	x
28	1	28	28	Left Sphere Sign	“+” or “-“
29	6	29	34	Left Sphere	xxx.xx
35	1	35	35	Left Cylinder Sign	“+” or “-“
36	6	36	41	Left Cylinder	xxx.xx
42	3	42	44	Left Axis	xxx
45	7	45	51	Left Prism	xxxx.xx
52	1	52	52	Left Base	x
53	5	53	57	Right Add	xx.xx
58	5	58	62	Left Add	xx.xx
63	18	63	80	Blank	

Response Disapprove. The DSMO members reached out but did not receive business justification from the industry for inclusion of vision prescription information as necessary for the adjudication of vision claims.

1176 Professional Claim (HCFA 1500) 9/12/2012

Request ASC X12 TR3 005010X222 for submitting professional claims or encounter reports (837p) permits the inclusion of Condition Information in multiple HI segments with HInn composite -01 containing a value of "BG". When such segments are present, HInn composite -02 may contain a value that identifies any NUBC code list. Unfortunately, HInn composite values -03, -04, -05, -06, -07, -08, and -09 are all listed as Not Used, thus prohibiting inclusion of any data values from any NUBC code list.

Suggestion Add language to the description of HInn composite -02 that requires use of HInn composites that are suitable to the type of NUBC code list data values being included in a transaction, and make HInn composites -03, -04, -05, -06, -07, -08, and -09 Situational rather than Not Used.

Response Disapprove. This segment is correct as is; no additional value is needed with a Condition Code.

1180 Professional Claim (HCFA 1500) 10/1/2012

Request In order to remain competitive and to best service its members, it is imperative that 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 payers by 2015 if not managed appropriately. Employer groups are requesting utilization and cost management of specialty drugs from payers. Payers 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)

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.

Suggestion

Suggestion
Request for changing Situational Rule in 005010X222 (Professional 837) TR3 for 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:
Required when government regulation mandates or commercial carrier requires 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.

Response The DSMO was unable to come to a consensus on this request. If the submitter chooses to resubmit another change request, or provide more information on an appeal - more information about the business need should be provided, specifically to clarify if this request is for specialty drugs only versus all drugs, and if this is for prescribed medications or physician administered drugs.

1181 Pertaining to more than one, or not sure 10/30/2012

Request RFI # 1672 was opened with X12 regarding the ability to report NHRIC's in the 837P. The response from X12 was that '....if there is a business need to report this information that it be submitted through the DSMO process....'

Description of RFI 1672 to X12:

NHRIC's - National Health Related Items Codes - Are assigned to Medical Devices by the FDA. They are different from NDC codes.

With HCPCS code J7321, some payers are looking for the NHRIC code (08363-7761-01 for this example) which they are mistaking for an NDC code. We are experiencing this same issue with other medical devices which are typically injections used for orthotic purposes.

How can this be reported in the 837P 5010? I did not find a segment for this code and it can not be sent in the 2410 loop LIN segment because these codes are not listed in code set 240 for NDC codes.

Suggestion Our clients are reporting the NHRIC code in the 2400 LIN segment.

Would it be possible to add a qualifier and code set for NHRIC codes in the 2400 loop LIN segment of the 837P transaction and any other transaction that could possibly utilize this?

From the FDA:

National Health Related Items Codes (NHRICs) and New Drug Codes (NDCs):
New Drug Codes (NDCs) do not apply to medical devices. Instead, National Health Related Items Codes (NHRICs) are used to uniquely identify medical devices. The NHRIC is comprised of two components - the labeler code and the sequential number. The former is obtained by manufacturer application to the FDA. When this labeler code is obtained, the manufacturer completes the product by assigning a sequential number for the medical device. When this is completed, the manufacturer assumes ultimate responsibility of maintaining the NHRIC number. Below is a link describing NHRICs, as well as the NHRIC database. You may use the latter to search for the NHRIC number.

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/ucm161456.htm

Response Disapprove. The DSMO disapproves this request because the code set is not a HIPAA adopted code set. The submitter is invited to resubmit a change request after the FDA has issued final regulations for unique device identification. The unique device identification could replace the use of the NHRIC. The submitter is then requested to include clear business justification and specific usage for the use of NHRICs in each transaction in the request in conjunction with identifying the code set(s) being used for NHRICs under HIPAA.