e-Prescribing Standards Analysis Working Document

This set of worksheets represents a compilation of testimony that assisted the National Committtee on Vital and Health Statistics (NCVHS) in preparing its first set of recommendations for electronic prescribing standards.

(Please note, not every standard identified in this worksheet necessarily has been or will be recommended by NCVHS to become a national standard. A second set of recommendations for electronic prescribing standards will be developed by NCVHS in March 2005.)

This working document incorporates testimony from hearings in March 30-31, 2004, May 25-27, 2004, July 28-30, and August 17-19, 2004. It also incorporates responses from a survey sent to standards development organizations, developers of identifiers and terminologies, and other

Types of Identifiers	Existing Identifier(s)	Extent Identifier in Use	Gaps and Limitations Identified by Testifiers	Summary of Responses on How Gaps and Limitations may be Addressed	Address in: Near Term	Address in: Long Term
Identifiers						
Prescribers (e.g., Physicians, Others)				HL7 v2.x does not define person identifiers. Existing HL7 v2.x data types support a wide range of identifiers. Any "new" identifiers (not presently sent in known HL7 v2.x message installations) will need to be assessed, but typically can be accomodated by terminology (code table) updates rather than structural changes.		
	DEA	Used by every prescriber that has one	Not every prescriber is authorized to have DEA; DEA required on controlled substance claims. Can NCPDP HCIdea accommodate variability of DEA presence?	NACDS notes that if DEA approved number for e-Rx, not all prescribers have that number. Pfizer offers that if DEA use cannot be expanded, it should not be required on Rx except for controlled substances. HCIdea is recognized as potential matching source by Pfizer, SureScripts, and others. NCPDP supports all DEA numbers associated with a prescriber as well as all practice locations in the HCIdea database		
	NPI	HIPAA requirement. Will not be used for 1+ yrs	Because the NPPES does not include credentialling, how will prescriber's credential be confirmed? HIPAA NPI has no embedded content. Is inclusion of the NPI necessary in e-Rx? Can NCPDP HCIdea accommodate inclusion of NPI?	ASC X12N notes that today DEA and/or NCPDP HCIdea can continue to be used, but if e-Rx trx becomes a HIPAA requirement, the NPI would be required. In this case, the NPI wouldhave to be mapped to their prescriber files or NCPDP would have to crosswalk NPI to the HCIdea. NACDS does not believe NPI is necessary for e-Rx; Pfizer does not believe it is suitable for e-Rx. NCPDP notes it is not apparent yet if level of NPI will support e-Rx, but has programmed the HCIdea database to house the NPI for each prescriber when it becomes available.		
	State license number	Unique to state	If state license number is included in NPS, does every provider included in NPS have a state licensure number, or must this be accommated via another means?	ASC X12N notes that state license is not a required field in NPPES, therefore the NPI cannot be relied upon as a source of valid licensure. NACDS notes there is likely to be a gap between providers with state licenses and those covered in the NPPES. SureScripts notes that state license numbers are not required for e-Rx. NCPDP supports use of state license numbers, where appropriate.		
	Trading Partner ID (in NCPDP)	Unknown	Does HCIdea fully substitute for trading partner ID?	ASC X12N notes that most trading partners (TP) do not use IDs such as HCIdea because the TP may not be the prescriber (rather a CH). NCPDP SCRIPT does not have a "TP ID" as the identification of the prescriber is at the PVD Segment level and identifies the prescriber using standard X12 values. Rx Benefits Coalition and RxHub suggests that use of HCIdea should be piloted to determine if TP ID can be fully elminated. SureScripts uses proprietary physician identifier and believes HCIdea could replace this if it meets all their requirements.		

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Physical location where medical record associated with prescription is maintained	HCIdea (developed by NCPDP)	One Medicaid agency is requiring	What is cost of file? What is updating process and timeliness? How does prescriber get access? Does location need to be included in one identifier or as a separate identifier? What is assurance that DEA and NPI will be cross referenced? Does this always replace a trading partner ID?	ASC X12N asks how HCIdea crosswalks to DEA, when DEA is issued on a location basis (i.e., HCIdea 1-1 with DEA or 1-many?). NACDS does not believe HCIdea is necessary for e-Rx. Pfizer recommends HCIdea be considered the unqiue ID methodology for prescribers and deails worked out for 2006, including potential for underwriting the IDs for Medicare physicians.		
				NCPDP reports the cost varies depending on class of trade; there are no definitive plans to notify prescribers of their HCId number. (DEA numbers are already cross referenced, and NPI will be cross referenced when available.)		
				HL7 notes that location identifiers are typically handled with different data types in HL7 than person identifiers. If HCIdea is a composite "person at a location," that should be able to be accomodated with current data types. However, the specific application and implications will need to be assessed.		
	Communication Identifiers (Phone, email) in NCPDP SCRIPT Provider Segment	Unknown	Does this serve as a separate location identifier?	NCPDP SCRIPT contains prescriber identifier, full name, specialty, full address, clinic name, phone numbers. NCPDP does not understand "separate location identifier" and notes that each transaction can specify the prescriber and the location information deemed appropriate to be populated on the transaction. SureScripts notes that the additional information is used to help identify proper prescriber because there is not a universally accepted unique identifier.		
				HL7 v2.x data types and code tables support multiple commuinication identifiers (e.g., phone, email, beeper, etc.)		
Name of practice group, clinic, office, etc. to which prescriber belongs	NCPDP SCRIPT	Unknown	Does NCPDP support a specific identifier for this or is it a part of a message segment?	NCPDP SCRIPT contains the "clinic" name as part of Provider Segement, which may be different for the same provider prescribing in different settings. SureScripts suggests a unique identifiers is not required but could be useful.*		*
	HL7			HL7 v2.x can support both the name of an organization and an assoicated identifier in a single data type. Again, HL7 v2.x does not define these identifiers, but support for "Name of practice group …" does not appear to be an issue in HL7 v2.x.		
	NPI	HIPAA requirement. Will not be used for 1+ yrs	Is this a part of NPI/NPPES and accessible to e-Rx, or is a separate identifier needed?	ASC X12N and Pfizer notes that in the NPPES there is no tie to the practice in which the individual is affiliated, and for organizations there is no tie to a parent organization.		
Authorized agent identifier (i.e., person other than prescriber, such as PA, nurse)	NCPDP SCRIPT	Unknown	Does NCPDP support a specific identifier for this or is it a part of a message segment?	NCPDP SCRIPT contains "Designated Agent" full name as part of Provider Segment. At this point, there is no standard identifier, but standard could be modified to support an identifier and the code set (near term).* Since no identification system is available, any modifications to the standard would be long-term until the system is developed. SureScripts does not see a need for a specific identifier.	*	X
	HL7			HL7 notes that existing fields in HL7 v2.x order segments are available to identify both the prescriber, an enterer, and a verifier. Assuming that the authorized agent does not have prescriptive authority, they would most likely be identified in the 'enterer' field.		

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	NPI	HIPAA requirement. Will not be used for 1+ yrs	Is this a part of NPI/NPS and accessible to e-Rx, or is a separate identifier needed?	ASC X12N would need to add an "Authorized Agent" if required in 270/271.		ASC X12N >1 yr
Supervisor identifier (e.g., co-signer)	NCPDP SCRIPT	Unknown	When will this future enhancement of SCRIPT Segment be available?	NCPDP SCRIPT is being balloted now with this modification for use by end of 2004	X	
	HL7			HL7 notes that while the identifier for a Supervisor can be supported with HL7 v2.x data types, this standard does not currently have an explict field to support the concept of a Supervisor/co-signer. HL7 v3 has mutilple "person roles" which would accommodate Supervisor/co-signer. Interium enhancements to HL7 v2.x could be added in the near term		
	NPI	HIPAA requirement. Will not be used for 1+ yrs	Is this a part of NPI/NPS and accessible to e-Rx, or is a separate identifier needed?	ASC X12N would need to add an "Authorized Agent" if required in 270/271.		ASC X12N >1 yr
Dispensers (e.g., Pharmacies)	NCPDP Provider ID (formerly NABP)	Widely used for decades	Used for processing and payment of claims. Is this identifier unique per pharmacy location for routing e-Rx, or must Pharmacy Name, Pharmacist's Name, Address, and Communication Identifiers be included?	NABP notes that NCPDP Provider ID is well established for Rx claims and it is important that it be flexible enough to accunt for new practice settings. A standard should not mandate that the NCPDP Provider ID preempt state license number or conflilct with any state licensing requirements. NACDS believes NCPDP Provider ID is all that is required. NCPCP Provider ID is unique per pharmacy location; the other demographic fields can be sent on trx for further verification.		
				HL7 can support in v2.x and v3 data types		
	NPI		Will the NCPDP SCRIPT accommodate the dispenser NPI?	NCPDP SCRIPT supports the NPI as a valid code set now.		
Patient verification of identity by prescriber	NCPDP SCRIPT Patient Segment: Pt name, DOB, gender, SSN, Clinic Specific ID, Address, Communication Identifiers		Are these the most likely data elements to identify a patient?	Pfizer notes that for Medicare, the HIC should be used, with the combination of the HIC and its identification as HIC. The combination of domain plus ID can serve the greater role of identifying patients in trxs, provided that a controlled vocabulary of domains be appropriately maintained and published. Rx Benefits Coalition notes that industry is moving away from SSN; RxHub uses name, DOB, gender, and zip code; SureScripts uses name, DOB, gender, and SSN. NCPDP notes that patient would be identified by an ID (were a national ID available), name, DOB, and gender. Address and phone numbers are available in current use for further validation and sharing of demographic information.		
	HL7			HL7 v2.x PID segment, and v3 Patient class current support a wide range of demographic information, including the attributes specificed.		

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Patient identification used in e-Rx transaction	Medicare ID #	Medicare only	Can NCPDP handle multiple different identifiers?	NCPDP SCRIPT supports Medicare ID, as well as other IDs; how many identifiers need to be shared in a given trx would be governed by business case. HL7 v2.x and v3 can support multiple identifers for patient		
	Patient unique ID in health plan	Proprietary in every plan	Does this require standard across all plans?	NACDS sees this as a gap. RxHub uses a model that can use any plan formatted identifier for the patient, which is passed back on the eligibility trx. NCPCP SCRIPT supports patient identifiers, cardholder information (including ID), and relationship of patient to cardholder. HL7 v2.x and v3 can both support multiple identifier for the patient. Proprietary identifier can be included, but the ability of the receiver to understand/utilize a proprietary identifier is beyond the scope of the standard.		
Prescription Drug Program (PDP) Cardholder/ Subscriber	Cardholder unique ID in health plan		Does this require standard across all plans?	NACDS sees this as a gap. Rx Benefits Coalition and RxHub does not believe a standard across plans is required. The cardholder information is passed back on the eligibility transaction in the RxHub model. However, the unique plan ID is the ID typically used by the POC vendor for plan access to data. NCPDP SCRIPT supports the cardholder ID and name, and does not believe there is a need for a standard across all plans, but standard ways of obtaining that information (benefit cards, eligibility retrieval, etc.) HL7 see above patient identification in e-Rx		
Personal representative of patient (e.g., parent of minor, guardian, caretaker)	?		If different than cardholder, how is this represented in transaction, what is the business case for this?	NCPDP SCRIPT does not address this. HL7 v2.x has limited ability to support patient agents. Some agents (parent, gardian) are supported by specific fields. Additional agents types may require the addition of fields or the development of alternate structures. HL7 v3 can support a wide variety of patient agents, or persons that have a defined relationship to the patient.		HL7: 6-12 mos
Health Plans			HIPAA Health Plan Identifier NPRM expected in Nov 2004. Anticipated problem if no hierarchy included. Will "health plan" include PDPs, PBMs, subgroups of benefits, etc.?	ASC X12N notes that it is unlikely that a hierarchy will be created. NACDS is concerned that the HIPAA Health Plan ID will not be able to identify plan groups and PBMs. NCPCP notes that billions of pharmacy claims are submitted with use of BIN/Processor Control Number/Group relationship, also placed on the standard Pharmacy ID Card. Unclear what impact and at what level Health Plan ID will have - whether it would cross-reference to the BIN/PCN/Group or BIN/PCN or BIN? Unclear if NPlanID will assist in COB or impact to e-Rx		
				To date, all necessary identification of Health Plans has been supported in v2.x and is included in v3. However, the "hierarchy" of the health plans must has not been necessary within the message. If the hierarchy must be included, then it will be necessary to understand the structure of that hierarchy in order to accomodate it in HL7 messages. This should not be significant for HL7 v3, but may require significant		

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Prescription Drug Program (PDP)	NCPDP Pharmacy ID I.G. for INCITS	Widely used in claims; not widely used in e-Rx.	If prescriber uses X12N for eligibility verification, is this identifier valid? Will it identify subgroups?	ASC X12N would need to add a code for PDP if required in 270/271. An inquiry could use an additional identifier such as Group, Policy, or Plan Number existing today.* NCPCP will create a guidance document to map the Pharmacy ID Card information to the appropriate fields on the X12 270/271. SureScripts notes that a standard across all plans is not needed, but there is a need to ensure prescriber sends information on the e-prescription. HL7 unclear on relationship to v2.x or v3, but will investigate further	* NCPCP X	ASC X12N >1 yr
Benefit Program (subgroups)				ASC X12N would need to add a code for Benefit Program (subgroups) if required in 270/271. An inquiry could use an additional identifier such as Group, Policy, or Plan Number existing today*.	*	ASC X12N >1 yr
Pharmacy Benefits Manager (PBM)	NCPDP Telecom includes unique identifiers (BIN/Processor Control Number/Group ID) to identify benefit program. Also in SCRIPT	Widely used in Telecom; not used in SCRIPT	Is this needed for prescriber eligibility verification? If so, is this valid for use in X12N?	ASC X12N would need to add a code for PBM if required in 270/271. Today, the Information Source is identified as the entity who holds the information needed and is responding.* Rx Benefits Coalition notes this is used in processing a claim, nor for e-Rx.	*	ASC X12N >1 yr
Provider Directory (Entities know which are available to receive electronic prescription messages)	NCPDP SCRIPT-based	Proprietary usage		NCPCP will facilitate bringing the industry together to modify SCRIPT to support communication of prescribers, nursing facilities, and pharmacies that are available electronically, which could be available within one year from start of project	X	
	X12 274 health Care Provider Directory	Unknown		Research utilization of X12 274 Health Care Provider Directory transactions		X
Formulary Identifier				MediMedia recommends the creation of a standard formulary identifier. It defines a formulary as a list of medicines and a set of basic rules on how to interpret the list. It believes creating a list of formularies without specific patient coverage information is a practical and efficient way to speed adoption of e-Rx. Health plans/PBMs could place the formulary identifier on cards that would link a patient to a specific formulary		

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Messages							
Prescriber Initiated Messages							
New prescription from prescriber to dispenser	Clinical drug being prescribed	NCPDP SCRIPT and HL7	Approx 3% of prescribers have true e-Rx capabilities (Rx Benefits Coalition and RxHub believe percent is higher but do not have any other data	Test RxNorm use and mapping to NDC in demo	NLM believes that the message content of the NCPDP SCRIPT can appropriately be the RxNorm clinical drug.		
					NACDS, Pfizer, Rx Benefits Coalition and RxHub, and SureScripts believe RxNorm must go through 2006 pilot. Medi-Span/WKHealth would like clarification of which term types of RxNorm are expected in demo		
					FDB is committed to supporting and cross-referencing to RxNorm; would like to see use cases created and validated prior to implementation. It is important that the intent of the physician's prescription is not lost when proprietary drug IDs are translated from a physician order entry system into RxNorm identifiers for e-Rx purposes and then translated back into drug knowledge base identifiers used within a pharmacy management system for order fulfillment. To support "dispense as written" prescirptions, drug knowledge base providers will also be required to link name based identifiers (e.g., FDB's MedID) to RxNorm's "Semantic Branded Drug" (SBD). This is critical, as UMLS does not currently provide a link between the NDC and the RxNorm SBD (only NDC links to the generically named "Semantic Clinical Drug" (SCD) are provided within UMLS). Without a SBD link to NDC, brand-specific structured product labeling can't be retrieved and "dispense as written" orders must be manually reviewed by the pharmacist.		
					NCPDP SCRIPT supports the required prescription information from the prescriber, and information to facilitate processing. Fields include drug name, form, strength, count, unit of measure, DAW, number of refills, diagnosis, a drug identifier, etc. These fields should continue to be used as applicable. Recommend further analysis of RxNorm for the different e-prescribing business cases. If it's use fits the need, the standard can incorporate whatever data fields/code values will be needed to represent the industry usage. If these factors are in place, whatever is determined should be tested in demonstration projects.		
					ASTM CCR provides a detailed map of the prescription at a greater level of detail than NCPDP Script (particularly regarding the 'sig' portion of the prescription). The CCR maps very closely to SureScripts and covers all fields in NCPDP Script (but, as above, at a greater level of detail). The CCR prescription is easily 'dumbed down' to NCPDP Script through XSLT translation. Physicians look at e-prescribing as more than just sending a prescription to the pharmacy to be filled. They see it as medication order entry, which can result in the administration of a medication in their office, patient's home, hospital, in a long term care facility. CCR supports all of these functions with a single unified and comprehensive data tagging approach for medications. Of particular importance in this regard is making the 'sig' component granular and highly configurable. The CCR workgroup has identified drug naming (mapping of generic drug names) as a critical issue that has not been addressed yet by NDC or RxNorm.		

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					HL7 notes available in current HL7 v2.x messages and mapping between NCPDP and HL7 underway.	Q1 2005	
Cancel request from prescriber to dispenser		NCPDP SCRIPT and HL7	May not be included in all e-Rx products. Rx Benefits Coalition and RxHub note this is not used in industry today; and RxHub has not implemented at the request of its participants	Does this need to be included in demo?	NCPDP and ASTM recommend inclusion in demonstration; NCPDP suggests with educational material prepared by CMS to show ROI, benefits.		
					SureScripts does not see need to test in 2006 pilots		
					HL7 notes available in current HL7 v2.x messages; mapping between NCPDP and HL7 will be addressed in later phases of project		12
Request for return receipt from prescriber to dispenser		NCPDP SCRIPT and HL7	May not be included in all e-Rx products. Rx Benefits Coalition and RxHub support, but not widely used because retail pharmacies do not want to pay for the extra trx.	Determine adequacy and usability of NCPDP Request for Return Receipt. Should acknowledgement of receipt be automatic?	NCPDP SCRIPT supports the real-time requests with responses. For example, new prescription request has a response of status or error. Change request has a response of change response or status or error. The Verify (return receipt) can be used, but does not have to be. It should be considered a lower priority and only for those entities that deem needed use.		
					Surescripts does not believe this should be automatic. The networks respond with error messages when a problem is encountered and acknowledging every message contributes to excess traffic and costs. The Verify message can be used but is not in current implementations.		
					Rx Benefits Coalition and RxHub note that the Status transation has been implemented, but does not fully meet the requirements that a Verify message does.		
					HL7 communication- and application-level acknowledgements are available in current HL7 v2.x and v3 messages		
Eligibility inquiry from prescriber to payer/PBM and response from payer/PBM to prescriber	Information about a patient's payer/PBM and coverage, including links to patient including unique ID, **formualry** and **benefit** files, cardholder ID and cardholder information	ASC X12N 270/271	Unknown. Rx Benefits Coalition and RxHub notes this is used by all participants in RxHub model	Does X12N supply all information identified in content? How does prescriber get NDC code currently required in 270 (EQ02-1, 235 and 234)?	ASC X12N notes prescriber would know NDC from code list. However, EQ02-1 is only required if the EQ02 Composite is used. If this composite element is used, and NDC (code value N4) is selected, NDC code must be in EQ02-2 (EQ02-3, etc). There are no explicit codes to indicate the formulary or benefit numbers in the 270 or 271. Cardholder ID and Demographic Information can be collected in 270 and returned in 271. Where there are gaps that need to be transmitted in 271 (such as need for formulary or benefit identifiers) transaction has free form message segment that could outline details currently not codified. It will take >1 yr to have values added to X12 and IG/TR3		Std & IG > 1 yr
					Rx Benefits Coalition and RxHub notes its **Eligibility** transaction supplies all of the required information about a patient's eligibility and links to formulary and benefit information. An NDC is not required in the RxHub model, because at the time that the eligibility request/response are performed, the prescriber has not chosen a particular drug to prescribe.		
					HL7 notes generally not an HL7 message in the US, but HL7 messages are embedded in X12N messages when supporting clinical information (attachements) are needed. These attachements are available now.		
					NCPDP notes there is current usage of X12 270/271 in e-Rx and recommends inclusion in demo with educational material prepared by CMS to show ROI, benefits.		

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		? Pre-load	Unknown	Extent used? Is there another standard needed?	HL7 notes not presently in the HL7 domain. HL7 Master File messages can be adapted for this purpose if determined to be a preferred means for implementation.		Unkn
					In the RxHub model, it is not necessary to pre-load eligibility information to the POC application, as the patient is located during the processing of the eligibility transaction using the RxHub Master Patient Index (MPI) functionality. (Note that RxHub can run the 270/271 transactions for a list of patients with appointments in advance of the patients visiting, but this is not considered a "pre-load" as the population is a small subset of the health care provider's aggregate patient list.)		
		NCPDP Telecom	Not used by prescribers		HL7 notes not presently in the HL7 domain. HL7 Master File messages can be adapted for this purpose if determined to be a preferred means for implementation.		Unkn
					ASTM CCR provides a way to extract eligibility data from EHRs and PMSs and convert it to X12, HL7, or NCPDP messages.		
Medication history with other provider sources	Medication list compiled by provider and recorded in EHR or CCR. Includes drug samples, compounded drugs, etc.	HL7 from EHR module	<10% adoption of EHRs	Can list be reconciled with list from PBM/payer?	NCPDP notes that from testimony, there are participants exchanging medication history from the payer using a modified NCPDP SCRIPT, which is then being mapped to an HL7 message for the prescriber. NCPDP will facilitate bringing together the industry to approve modifications to the NCPDP SCRIPT Standard to support the transfer of medication history from payers for the treatment of patients. This process is estimated to complete in approximately one year from the start of the project.	X	
					Existing HL7 v2.x and v3 messages could serve to communicate medication history between providers. Reconciling the list with PFM/payer is an application/process issue that is not within the domain of HL7. Current mapping efforts between NCPDP and HL7 may help with eventual PBM reconcilliation.		Unkn
					Rx Benefits Coalition and RxHub notes the HL7 medication list has as yet very low adoption. Although it would have to be studied, the RxHub developed message likely could be converted into HL7 format.		
					FDB notes that claims-based medication history is NDC based, so prescriber systems will require the use of up-to-date NDC-based database content to take advantage of this information.		
					ASTM notes that the issues of list reconciliation go back to the discussion of drug naming conventions and semantics. There needs to be exact reconciliation between the generic name of medications, something not covered in a discrete way by NDC or RxNorm. As discussed elsewhere, reconciliation of drug names from lists from disparate sources is critical for patient safety.		
		ASTM/HL7 CCR	New	ASTM is content only; HL7 is in process of developing a message format.	HL7 notes that CCR development continues. Availability by the demo is possible, but for the purposes of this document is indicated at long term (12 months)		12
					Rx Benefits Coalition and RxHub note this standard does not exist today. See RxHub medication history transaction from payor to prescriber disussed below.		

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					ASTM notes the CCR medication section is defined, structured, and mapped to provide a complete and detailed medication list as well as to support a medication history (often as important in prescribing as the current list). The CCR can be thought of as 'content only', which is the intent of the structure, but it is a messaging format because it is well-formed XML. XML is considered, by the wider high-technology industry, as a content as well as messaging format. Note that the CCR can also be used as a segment within an HL7 message or as an HL7 CDA 'Template.'		
Medication history from patient to prescriber	Medication list maintained by patient in a PHR; might include supplements, OTC, etc.	HL7 from EHR module; screen entry	Unknown	Does this need to be included in demo?	Existing HL7 v2.x and v3 messages could serve to communicate medication history from PHR to EHR/PMS/etc. This would require the existance of a PHR (or a suitable mockup) in order to demonstrate.		
					NACDS believes this is a gap that should be tested in pilot		
					Pfizer and SureScripts view this as a long-term issue; with Pfizer noting a structured, patient-driven medication list being an important part of a PHR and messaging standards for transferring this information to and from the PHR should be established and tested.		
					FDB believes this should be included in demo if any type of clinical screeining is to be demonstated. This medication history can be maintained in the e-Rx application or be resident in a physian practice management system/EHR and made available to the clinical screening application		
					Rx Benefits Coalition and RxHub note this standard does not exist today. See RxHub medication history transaction from payor to prescriber disussed below.		
					ASTM views this as needing to be included in the demo. The patient, family, or caregiver is the only valid source of what the patient is actually taking, which is often very different from what the patient has been prescribed. As noted, knowledge of OTC and supplement data are becoming more and more critical in prescribing to protect patient safety. The CCR supports patient data entry and management of lists (including medication list) and clearly defines source (patient, family, caregiver, physician, etc.). The CCR also supports OTC and supplement data entry and management in the medication list.		
Medication history from prescriber to dispenser		What standard (HL7 or NCPDP)?	Unknown	Is this a necessary message? What content is required?	NCPDP notes if business needs are identified, NCPDP is willing to work with the industry to modify the SCRIPT Standard so that pertinent information is relayed from the prescriber to the pharmacy when necessary.		X
					Pfizer and SureScripts note this is a desirable message but work must be done on this before there is a suitable and stable standard for accomplising this.		
					Rx Benefits Coalition and RxHub note this standard does not exist today. See RxHub medication history transaction from payor to prescriber disussed below.		
					FDB notes the dispenser, prescriber and in many cases the PBM will all be doing clinical screening based on the medication history they have available. In a perfect world there would be a Central Data Repository acessible by any provider. Since this does not exist now and will not exist in the near future we should not require transfer of medication history from prescriber to dispenser. It would greatly complicate an already complicated scenario		

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					ASTM views this as a very important and necessary message. This is the crux of e-prescribing - making sure all players in the food chain (including the dispensing pharmacist/pharmacy) have the correct, up-to-date, and complete data on the patient. This is the core goal relative to providing for patient safety. Currently the dispensing pharmacist has better data than the physician as they have access to what medications have been dispensed from the PBMs. They do not, however, have data on all the medications that may have been dispensed by hospitals, ambulatory care centers, clinics, or as samples. They also do not necessarily know what is being administered in clinic (chemotherapy, Procrit, etc.) or in the home health setting (Lovinox, for example), or alternative/chronic/step-down care setting (nursing, rehab, and long term care). Finally, they do not know if what has been prescribed and dispensed is actually being taken - particularly when a family member and not the patient picks up the prescription.		
					NACDS believes all current medications should be transmitted.		
					Existing HL7 v2.x and v3 messages could serve this purpose, but the question of necessity is pertinent. Also, many dispensing system (especially those outside for integrated health care systems) would need to adapt to the HL7 messages.		
Medication history from Payor to prescriber	Medication History list from payors based on claims processed by the payors	NCPDP SCRIPT Based Standard/HL7 based messaged	Utilized by all participants in the RxHub Model		The RxHub developed message contains a list of medications processed by payor(s). In the RxHub model, the prescriber/hospital gets information from all payors where the patient has an active benefit.	X	

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Benefits (DUR) inquiry from prescriber to payer/PBM and response from payer/PBM to prescriber	Coverage limitations, such as drug exclusions; prior authorization; step therapy. Patient copay information specified as tiers or dollar amounts based on general criteria	ASC X12N 270/271	Unknown	Does ASC X12N 270/271 support all benefits information identified in content?	ASC X12N notes all benefits identified are supported except for grams and ml doesages for step therapy. For step therapy, use of the HSD segment can identify a delivery pattern (such as 2 units, per day for 1 week). The DTP segment can identify the beginning and ending dates for each step. The HSD cannot currently identify steps if measured in grams or ml. The following categories are supported for tiers with the 004010 version of the transaction: Free Standing Prescription Drug Mail Order Prescription Drug Brand Name Prescription Drug Generic Prescription Drug The following additional categories have been added to the 005010 version: Mail Order Prescription Drug: Brand Name Mail Order Prescription Drug: Generic Brand Name Prescription Drug - Formulary Brand Name Prescription Drug - Non-Formulary Generic Prescription Drug - Formulary Generic Prescription Drug - Non-Formulary		Std & IG > 1 yr
					Rx Benefits Coalition notes that the X12 271 transaction was not designed to pass back a list of drugs and related information.		
					NCPDP recommends CMS discussing with current implementers to determine which eligibility and which benefit pieces are exchanged.		
					ASTM notes that current PBM DUR processes are supported by X12, but as more sophisticated models emerge, a greater level of patient clinical detail will be needed to define payment. For example DUR will focus more and more in the future on 'appropriate therapy' with the payment mechanism being the only control the PBM has over the provider. Truly effective DUR will require medication lists, problem lists, procedure lists, allergy lists (is an expensive AB being used inappropriately when an allergy is claimed?).		
		Proprietary Pre-load	Unknown - Used by all participants in RxHub model	Does pre-load support all benefits information identified in content? Is there another standard needed?	NCPDP will facilitate bringing together the industry to approve a new standard that allows the transfer of formulary and benefit coverage information from the PBM/payer to the prescribing application to be downloaded and utilized in a real time mode during the prescribing process. This process is estimated to complete in approximately two years from start of the project.		X
					Rx Benefits Coalition and RxHub notes the file format supports all information identified.	X	
	Dosage adjustments (age,height, weight, and gender)			In ASC X12N 270/271?	ASC X12N notes age can be calculated from the DOB and exists today, gender code (M, F or U) exists today. No code value or element is available for dosage adjustments today. Where there are gaps in the information that needs to be transmitted in the 271 response (such as the need for dosage adjustments) the transaction does have a free form message segment that could outline the details that cannot currently be codified.		Std & IG > 1 yr
					SureScripts notes that this and other interactions is clinical information, not benefit information.		
					ASTM CCR provides this.		
					NCPDP does not understand how DUR is part of benefits inquiry/response. Perhaps this is more of "patient profile" information? SCRIPT allows for the communication of DUR information between pharmacies and prescribers. 270/271 does not include this information as related to DUR. Perhaps the "DUR" is out of scope of the need?		

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	D-Drug			In ASC X12N 270/271?	ASC X12N notes identification of drug interactions cannot currently be coded explicitly. It is possible to identify a specific drug (via NDC code) as Non-covered with a text message indicating a drug interaction exists.		Std & IG > 1 yr
					ASTM CCR provides this.		
					Medi-Span/WKHealth requests clarification concerning DUR messaging because DUR would be done on the system where the e-Rx was generated.		
					NCPDP does not understand how DUR is part of benefits inquiry/response. Perhaps this is more of "patient profile" information? SCRIPT allows for the communication of DUR information between pharmacies and prescribers. 270/271 does not include this information as related to DUR. Perhaps the "DUR" is out of scope of the need?		
	D-Allergy			In ASC X12N 270/271?	ASC X12N, NCPDP, ASTM CCR - see D-D.		
	D-Lab			In ASC X12N 270/271?	ASC X12N, NCPDP, ASTM CCR - see D-D.		
	D-Food			In ASC X12N 270/271?	ASC X12N, NCPDP, ASTM CCR - see D-D.		
	Duplicate			In ASC X12N 270/271?	ASC X12N, NCPDP, ASTM CCR - see D-D.		
		NCPDP Telecom	Not used by prescribers		NCPDP Telecom would be used by prescribers who are billing pharmacy claims. NACDS asks if prescribers could use for DUR		
Formulary request from prescriber to DKB (real time)	Availability of lower cost, therapeutically appropriate alternatives	What standard?		Does this need to be included in demo?	NCPDP notes that this is an internal database look up (search/select statement) on a system, not standards. How formulary information is used in the e-prescribing environment can be demonstrated.		
					Rx Benefits Coalition and RxHub note that DKBs do not have formulary alternative information. This information is managed by the health plan or PBM. In the majority of today's electronic prescribing applications, formulary information is stored and accessed locally by the prescribing application. This could be looked at as more of a long term goal if/when requested by the prescribing applications.		
					NACDS, SureScripts, and FDB notes this is a gap and should be tested in demo. FDB further notes that formulary information and it's method of availablity should be defined by the payor and the prescriber through a business agreement. There are numerous ways to make this information available and the committee should not limit those methods.		
					Pfizer notes there is no standard method for structuring and pre-loading a formaulary, including prior authorization. This needs to be addressed in near term as it will be a signficant barrier to the adoption of e-Rx under MMA		
					ASTM note this is a critical workflow issue that SureScripts, RxHub, and the EHR and e-prescribing vendors are trying to solve. It should be a required part of the demonstration project.		
					HL7 Master File and Query messages could be a basis for this interaction. However, with no present work in this regard, it is unlikely that it could be established in time for the demo. Furthere analysis would be needed to determine a time frame for development		Unkn
Formulary and Benefit information					NCPDP will facilitate bringing together the industry to approve a new standard that allows the transfer of formulary and benefit coverage information to the prescribing application to be downloaded and utilized in a real time mode during the prescribing process. This process is estimated to complete in approximately two years from start of the project.		X

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Decision rationale for drug choice (when off-formulary, etc.) from prescriber to dispenser for dispenser use in submitting to payer/PBM		What standard?	Unknown	Does not have to be a separate message. Which message?	NCPDP notes that if business needs are identified, NCPDP is willing to work with the industry to modify the SCRIPT Standard so that pertinent information is relayed from the prescriber to the pharmacy when necessary.		
					Rx Benefits Coalition and RxHub notes the SCRIPT transaction allows for decision rationale information to be passed on the new prescription. This is not widely utilized today, so should be piloted.		
					NACDS views this as a gap and knows of no existing standard that carries this message.		
					Pfizer and SureScripts notes this should become part of the NCPDP SCRIPT as it can avoid call-backs to the prescriber		
					ASTM CCR with its 'Reference' ability linked to all data elements in the patient's clinical history provides an ideal vehicle to support decision rationale as well as appropriate decision making. It allows the payor to quickly validate the rationale without (in most cases) having to request 'additional documentation' from the physician, hospital, or other provider.		
					HL7 could embed decision rationale in the New Order (or Refill Authorization) message. Current HL7 messages could include as an Observation, but there is still a question of content and structure. Until issues of content and structure of Decision Rationale are addressed, timeline for development cannot be assessed		Unkn
Prior authorization request by prescriber to payer/PBM and response from payer/PBM to prescriber	Logical branching protocol specific to drug and benefits	ASC X12N 278	Not widely used for any purpose	Sufficient for drug prior authorization?	ASC X12N notes the 278 request/response provides limited support for requests for prior authorization of drugs. The transaction provides the ability to identify the drug using NDC or other HIPAA standard code sets. However, most physicians request drugs by name or formulary and have resorted to using a MSG segment (text string) to request the drug. The following URL provides information on workarounds recommended for limitations in the HIPAA implementation of the transaction. http://www.x12.org/x12org/subcommittees/X12N/N0210_DrugApproval_Req_278.pdf. The 278 supports codes sets that identify the patient condition/rationale for the drug as well as the ability to attach medical history information. The 278 does not support all of the identifiers noted under the identifiers tab and specifically does not currently support the DEA identifier. The 278 HSD segment does support the ability to express the dosage. In addition to the use of the 278 for prior authorization, one might use the 278 to enable the supplier to request permission to fill an order from an identified provider. The response conveys permission from the payer to the supplier to fill the order. The 278 notification could be used to send a copy of the prescription request/script from the provider to the pharmacy. It could also be used by the pharmacy back to the provider to notify the provider that the prescription has been filled.		

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					The pharmacy/supplier could use the 278 inquiry to determine if authorization has already been granted for the prescription. In addition, the 278 provides the ability for the prescriber to request to cancel, renew, extend, revise an authorization/order. While the traditional transaction exchange for a request/response is between a provider and a payer/UMO, the 278 standard does not limit the business entities that participate. For example, the request may be from the dispenser to the payer or between the prescriber and the dispenser. The dispenser response can indicate that the prescription/order has been modified by the dispenser/payer.		
					Rx Benefits Coalition and RxHub notes that interactive prior authorization for prescribers is not ripe for a standard; in particular, ASC X12N 278 does not support the complexity of prior authorization decision trees.		
					Pfizer notes they have not seen sufficient evidence that the X12 278 is sufficient for this purpose. There is a need to develop an apprpriate messaging standard for prior authorization adjudication		
					NACDS views this as a gap that needs to be tested in pilot		
Medical history from prescriber (any source, including EHR, CCR, PMS, etc.) to dispenser	See Medical History worksheet for possible detail	HL7, ASTM CCR, Others	New	Will HL7 EHR content and ASTM CCR content be ready for demo?	ASTM notes the CCR will be fully balloted (standard, data elements, implementation guide, and XML schema) by mid-Q4 2004	X	
					Pfizer believes this is beyond the scope of short-term objectives as it will require a signficant amount of investigation and coordination among SDOs.		
					NACDS believes patient could benefit if pharmacy had diagnosis and other relevant information		

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Dispenser Initiated Messages							
Change request from dispenser to prescriber	Result of DUR, incl guidance on height, weight, age (including days, weeks, months) of pt	NCPDP SCRIPT and HL7	Not used extensively	Does this need to be included in demo?	NCPDP notes that change request functionality should be included in demonstration, with educational material prepared by CMS to show ROI, benefits. Drug Use Evaluation and observation fields exist in the NCPDP SCRIPT Standard. Current industry participants should be queried to see if the DUR functionality is available for demo.		
					NACDS, Pfizer, Rx Benefits Coalition, and SureScripts believe demonstration would prove utility.		
					HL7 notes that this is available with current HL7 v2.x messages. Mapping between NCPDP and HL7 will be addressed in later phases of project		X
Refill/renewal request from dispenser to prescriber and authorization from prescriber to dispenser		NCPDP SCRIPT and HL7	Widely used	Does this need to be included in demo?	NCPDP notes refill/renewal functionality should be included in demonstration, with educational material prepared by CMS to show ROI, benefits.		
					HL7 notes this is available with current HL7 v2.x messages. Mapping between NCPDP and HL7 underway.	Q1 2005	
					Pfizer, NCADS, Rx Benefits Coalition, and SureScripts note this is in widespread use and noncontroversial; ready for use today. Pfizer, NACDS, and SureScripts note it may be useful to conduct ROI studies with respect to its benefits to prescribers as this serves to reduce many calls with pharmacies		
					ASTM notes this is critical to workflow and paperwork reduction. This is squarely addressed by SureScripts. The CCR and SureScripts support a level of detail in the drug 'sig' at a much more discrete (and important) level than NCPDP Script.		
Return receipt sent from dispenser to provider (for any transaction)		NCPDP SCRIPT Receipt Request and HL7	Unknown	Determine adequacy and usability of NCPDP Request for Return Receipt. Should acknowledgement of receipt be automatic?	NCPDP SCRIPT supports the real-time requests with responses. For example, new prescription request has a response of status or error. Change request has a response of change response or status or error. The Verify (return receipt) can be used, but does not have to be. It should be considered a lower priority and only for those entities that deem needed use		
					NACDS this could be automatic, but since there is a transaction cost, this is a logical place for federal funding support.		
					Surescripts does not believe this should be automatic. The networks respond with error messages when a problem is encountered and acknowleding every message contributes to excess traffic and costs. The Verify message can be used but is not in current implementations		
					HL7 communication- and application-level acknowledgments are available in current HL7 v2.x and v3 messages		
Fill status notification from dispenser to prescriber	Fully filled, partially filled, number of refills, not filled	NCPDP SCRIPT and HL7	Not used today. RxHub notes it is not used at request of RxHub's participants	Is this an automatic message, or only when prescriber requests it? Is there a trading partner agreement that can specify when to send?	An NCPDP task group will create further guidance about the use of these transactions.	X	
					NACDS believes there are policy decisions that could be informed by a demo		
					SureScripts notes this is rarely used at present and would have to be a trading-partner agreement message.		

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					Pfizer notes there are current limitations to this notification that need to be addressed in pilots. Pharmacies are often unable to track in their systems when a prescription is actually handed to the patient; they generally track when the eRx is filled (taken out of stock and put into a bottle), but this is not the same thing. The important data point to the clinician is when the Rx is picked up by the patient. There is also a continuing question about who will pay for this transaction. There could be interest among manufacturers to support this notification as it will aid in compliance and better care, but there is no sound mechanism for this support today. There are also liability questions from physicians about what would happen if they do not react to this new information. There needs to be some discussion about this liability as there isn't clear legal precedent around the issue.		
					ASTM believes this is more important to provider than a return receipt.		
					In HL7 messaging, the fill status message can be requested or sent upon dispense. This interaction would be based upon trading partner agreement. Fill Status is not included in the first phase of the NCPDP-HL7 mapping effort. It would be unlikely that it would be avaialble for the Jan 2006 demo		6-12?
Eligibility inquiry from dispenser to payer/PBM and response from payer to dispenser	Information about a patient's PBM/payer and coverage, including links to patient including unique ID, formuarly and benefit files, cardholder ID and cardholder	NCPDP Telecom	Few pharmacies conduct eligibility alone because real time claim provides eligibility, DUR, payment in		HL7 financial messges can also support eligibitility checking. However, NCPDP Telecom is predominant in the market and there is no apparent benefit to change from NCPDP		
Medication history from patient to dispenser		Screen entry in dispenser system		Is this a separate message (e.g., personal health record)?	NCPDP notes that internal display of software systems should not be addressed.		
					NACDS notes this is a separate message and should reflect federal and state OBRA '90 requirements		
					SureScripts note this is a separate message that does not have a place in e-Rx.		
					ASTM CCR fully supports medication history		
					HL7 notes that existing, or slightly modified, HL7 messages would be able to support transfer of medication history from patient to prescriber. Availability for the Jan 2006 demo would be dependent on the existance of PHR and EHR systems to interact on this basis.	X	

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Benefits (DUR) inqury from dispenser to payer/PBM and response from payer/PBM to dispenser	Coverage limitations, such as drug exclusions; prior authorization; step therapy. Patient copay information specified as exact dollar amounts based on plan-specific criteria.	NCPDP Telecom	Few pharmacies conduct eligibility alone because real time claim provides eligibility, DUR, payment in one trx.	Does Telecom support all content? Does this need to be included in demo?	NCPDP Telecommunication Standard supports the needed functionality for pharmacies to payers. The usage of this standard is demonstrated 4 billion times a year. It should not be included in demonstration.		
					SureScripts notes this is being used 4 B times annualy and does not need to be included in pilots.		
					Medi-Span/WKHealth requests clarification concerning DUR messaging because DUR would be done on the system where the e-Rx was generated.		
	Dosage adjustments (age,height, weight, and gender)				HL7 message could be adapted for this purpose. However, NCPDP Telecom is predominant in the market and there is no apparent benefit to change from NCPDP		
	D-Drug				NACDS believes this should be included in pilot		
	D-Allergy				Rx Benefits Coalition believes the current model works, although additional information could be included in the dispenser to payer/PBM communication, the need is not as critical as in other areas		
	D-Lab						
	D-Food				ASTM believes CCR is ideal for benefits.		
	Duplicate therapy						
Formulary request from dispenser to DKB (real time)		Proprietary Pre-load		Is this a needed message, or are all formulary reviews from a pre-load?	NCPDP notes that internal display of software systems should not be addressed.		
					NACDS and SureScripts notes that formulary information is received after claim submission		
					FDB notes that formulary information and its method of availablity should be defined by the PBM and the prescriber through a business agreement. There are numerous ways to make this information available and the committee should not limit those methods.		
					HL7 Master File and Query messages could be a basis for this interaction. However, with no present work in this regard, it is unlikely that it could be established in time for the demo. Further analysis would be needed to determine a time frame.		
Request for prior authorization to be sought by prescriber from dispenser to prescriber		NCPDP SCRIPT (and HL7?)	Not used; <2% of prescriptions require prior authorization; higher for Medicaid	Does this need to be included in demo?	NCPDP reports functionality is available.		
					SureScripts notes it is available, but does not need to be included in early pilots.		
					HL7 notes that if included in demo and part of the NCPDP-HL7 bridge demonstation, then interaction would need to be mapped into HL7 (probably an Unable to Dispense, with an indication that Prior Auth is required). This was not included in the initial NCPDP-HL7 mapping project and thus may not be available for the Jan 2006 demo		#####
Prior authorization from dispenser to payer/PBM		NCPDP Telecom			NCPDP current functionality		
					NACDS and SureScripts does not view this as a gap		

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Drug Knowledge Base Initiated Messages							
DKB from DKB vendor to prescriber DUR system (pre-load)		DKB proprietary		Is a standard message format needed?	HL7 notes that if SPL is a basic content requirement, then a standardized message may be a logic choice. Such a message could include sufficient local extensibility to support the DKB proprietary elements.		
					FDB does not believe a standard message format is needed. Style and format of DUR presentation should be driven by unique practice requirements and innovative DKB/presecriber DUR system vendor response to emerging market needs and opportunities. Electronic prescribing interoperability goals should be focused on the exchange of patient clinical findings, history and prescriptions in a standard messaging format with standard terminology, not on the standardization of commercial vendor applications and database content.		
					Rx Benefits Coalition and RxHub note that DKB vendors sell their reference information. They do not have real-time transactions to access the information. This information is stored locally by the software application using the information.		
					NACDS sees this a potential gap to be tested in pilot		
					ASTM notes this is a critical issue. Unless there is an exact match at the generic drug name level between medication lists, then proprietary DKB systems will not be able to interact with the same lists, or will make mistakes or overlook data. NDC and RxNorm do not adequately address this. In the real world of medicine, too many drugs are given at non-standard dosing, and too many are abbreviated. Naming conventions, even for generic names, are not standardized between DKBs. The CCR workgroup has identified this as a key obstacle to e-prescribing.		
DKB from DKB vendor to dispenser system (pre-load)	All elements required for DUR and Structured Product Labeling	DKB proprietary		Is a standard message format needed?	NCPDP notes pharmacies and payers alrady support drug databases for this information. See also HL7 note above		
					Medi-Span/WKHealth notes that due to differences among DKBs in the presentation and screening algorithms, it is not possible to create a standard for loading data and notes this may be outside of scope of MMA.		
					FDB does not believe a standard message format is needed. Style and format of DUR presentation should be driven by unique practice requirements and innovative DKB/pharmacy management system DUR application development response to emerging market needs and opportunities. Electronic prescribing interoperability goals should be focused on the exchange of patient clinical findings, history and prescriptions in a standard messaging format with standard terminology, not on the standardization of commercial vendor applications and database content.		
					NACDS sees this a potential gap to be tested in pilot		

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					Rx Benefits Coalition and RxHub note that DKB vendors sell their reference information. They do not have real-time transactions to access the information. This information is stored locally by the software application using the information.		
		NLM-FDA DailyMed		When will this be available?	NLM: See Terminologies		
					FDB notes that successful deployment of NLM-FDA Daily Med information will be dependent upon the integration of information either directly into DKB database content or via the linkage of NLM-FDA Web-Hosted urls directly to DKB identifiers. Secondly, implementation of Daily Med content in vendor systems will need to occur. Coverage of at least the top 1500 drugs is essential in order to cover the majority of prescription writing encounters.		
					Medi-Span/WKHealth notes that DailyMed is a delivery mechanism and asks if it will have a consistent format to allow automated upload? Also notes this may be outside of scope of MMA.		
Health Plan/PBM Initiated Messages							
Medication history from PBM and/or payer to dispenser		Proprietary pre-load		Is a standard message format needed?	NCPDP will facilitate bringing together the industry to approve modifications to the NCPDP SCRIPT Standard to support the transfer of medication history from payers for the treatment of patients.	X	
					HL7 notes that with some reservation on "PBM proprietary information," HL7 v2.x and v3 messages are available to support this interaction		
					Rx Benefits Coalition and RxHub notes that the PBMs do not currently initiate medication history messages, nor do they provide medication history to dispensers today. However, PBMs do perform DUR using the PBMs' own medication history information and thus the dispensers get the benefit of the PBMs' medication history information in a more accurate DUR.		
					NACDS notes this should be a standard message format.		
					ASTM notes CCR would be ideal for this message.		

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Medical history from plan to prescriber	See Medical History worksheet for possible detail	None		What standard(s)?	See HL7 and ASTM above. See also Rx Benefits Coalition and RxHub message from prescriber to payer/PBM to obtain medication history described above		
Patient demmographics to and from PBM/prescriber		RxHub message			Rx Benefits Coalition and RxHub identified messages between PBM, router, prescriber, and dispenser, many of which were RxHub batch loads, RxHub NCPDP-based participating providers message, new NCPDP-based message using SCRIPT segments/HL7 medication history messages, and local application data lookup from preload		
Request patient medication history from PBM to prescriber		RxHub message					
Load formulary and group benefit data from PBM to prescriber		RxHub message					
Extract prescriber location and identifer		RxHub message					
Load pharmacy demographic data from PBM to prescriber		RxHub message					
Extract pharmacy location and identifier data from PBM to pharmacy		RxHub message					
Load physician location and identifier data from PBM to pharmacy		RxHub message					

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Medical History							
Medical History	Patient demographics	HL7	<10% adoption of EHRs	Source?	HL7 v2.x and v3 supports patient demographics, provided the sending application has the information and incorporates it into the message. Source for any information in a message (HL7, NCPDP or otherwise) will always be limited by the function and use of the sending application. The standard cannot "address" the source issue directly, but can only make a conduit for the information available (the message).		
					Pfizer notes NCPDP SCRIPT only handles gender for transmission to dispenser.		
					SureScripts notes NCPDP SCRIPT supports demographic data such as address, telephone number, etc.		
					ASTM notes this is supported by the CCR, which could feed e-prescribing applications as can HL7. CCR demographic data can also be converted into and out of HL7 messages without problem. Note that for e-prescribing, 'demographic' data such as the preferred pharmacy for a patient are important to support. The CCR supports a very detailed level of demographic data, including pharmacy data, PBM data, payment and co-payment issues, and the breadth of administrative data needed to prescribe or administer medications in the inpatient and outpatient setting.		
	Diagnosis, problem list	HL7		Source? What level of detail is needed?	HL7 notes in addition to above, depending on the penetration of coded terminologies in the market, these elements may, or may not, be available as coded entries. Free-text strings would still be useful for the human user, but Descision Support applications will be dependent on coded terminologies		
					SureScripts notes that NCPDP SCRIPT supports transmission of ICD-9-CM codes, but the information is rarely transmitted by e-Rx partners.		
					ASTM CCR provides a complete problem list that includes problems, diagnoses, and conditions in a fully structured XML format. A high level of detail is needed - detail beyond that supported by ICD-9-CM, due to the need to understand the risks in medication prescribing and administration relative to the 'severity' of disease, not just the presence of the disease. The CCR provides support for problem attributes such as 'severity' as well as problem 'status' (active, inactive, chronic, rule-out, resolved, etc.) and other attributes that define per disease state how 'sick' the patient actually is. This is critical not just for common diagnoses and common risks such as renal failure and hepatic disease, but for management of complex diseases, polypharmacy, and complex disease-drug symptomatology and reactions/adverse reactions. Those of us practicing clinical medicine assume that we are seeing disease states that are actual manifestations of polypharmacy and not pathology, and this is something that e-prescribing will help us to address.		

Types of Message Formats	Message Content (MMA=Pink)	Existing Standard(s)	Extent Standard in Use	Standards' Gaps and Limitations Identified by Testifiers	Summary of Responses on How Gaps and Limitations may be Addressed	Address in: Near Term	Address in: Long Term
	Indication	HL7		Required for Structured Product Label	HL7 specifically support indication in the HL7 Structured Product Label specification.		
					ASTM notes indication is a mix of problems/symptoms which should come directly from an extract of the clinical record as supported by the CCR.		
	Allergies	HL7		Source?	HL7 - See Diagnosis, problem list		
					Pfizer and SureScripts believe NCPDP SCRIPT could accommodate if standard vocabularies and methodologies were developed		
					ASTM notes that as with Problems, the CCR supports complete and detailed allergy data, as well as adverse reactions. Listing an 'allergy' to penicillin for example without the inclusion of the reaction type or severity does not provide the level of clinical detail prescribing physicians need. A rash from penicillin will, for example probably not stop a physician from prescribing Keflex, whereas an anaphylactic reaction to penicillin might make the Keflex prescriber at least think twice. Codeine and Erythromycin 'allergies' commonly are not really allergies'; they are adverse reactions such as nausea or abdominal cramping. This distinction is very important and is fully supported by the CCR. Another key issues is 'source' - defining the source of the allergy information is important relative to the validity of the data. This is also fully supported by the CCR.		
	Height, weight, gender, and age (including days, weeks, months) of patient	HL7		Where will this information come from if prescriber does not have EHR, CCR, or PMS that incorporates this data?	Hl7 notes in addition to above, depending on the penetration of coded terminologies in the market, these elements may, or may not, be available as coded entries. Free-text strings would still be useful for the human user.		
					SureScripts notes NCPDP SCRIPT supports this demographic data, and some e-Rx partners use it.		
					ASTM CCR supports this, as does HL7 messaging. If these data are not available, then the e-prescribing systems need to support the entry and management of this data. The CCR XML format for these data would be ideal for exchange of these data between e-prescribing systems, as well as between e-prescribing systems, EHRs, and PMSs. The CCR fully maps to SureScripts and NCPDP Script in this regard.		
	History of present illness, past history, etc.	HL7		Source?	HL7 - See Diagnosis, problem list		
					ASTM CCR supports a complete snapshot of the patient's current and past medical history.		

Types of Message Formats	Message Content (MMA=Pink)	Existing Standard(s)	Extent Standard in Use	Standards' Gaps and Limitations Identified by Testifiers	Summary of Responses on How Gaps and Limitations may be Addressed	Address in: Near Term	Address in: Long Term
	Lab Results	HL7; NCPDP SCRIPT OBS Segment for future needs	NCPDP SCRIPT Segment Not used	A few drugs in a few states require pharmacy to have lab results. How is this transmitted through e-Rx?	NCPDP notes business needs have not been brought to NCPDP to enhance this Segment; but when identified, will work with industry.		X
					ASTM CCR supports a snapshot of the patients most recent lab results as part of the pertinent patient history.		
					HL7 notes Lab results are supported in existing HL7 v.2x and v3 messages, both in terms of ePrescribing and Medical History. Regarding Lab-Pharmacy interaction, this would not (necessarily) be in the context of ePrescribing. There are interfaces between Pharmacy and Lab applications, however these are typically in integrated health care systems. Again, the standards and messages exist to support Lab/Pharmacy messaging, but actual implementation will only occur when a business case (or mandate) exists.		
	Other clinical findings	HL7		Source?	HL7 - See Diagnosis, problem list		
					ASTM CCR supports clinical findings as problems, symptoms, and results, allowing detailed clinical data coverage.		
	Procedures	HL7		Source?	HL7 - See Diagnosis, problem list		
					ASTM fully supports with detailed tagging and coding by the CCR.		
	Vital signs	HL7		Source?	HL7 - See Diagnosis, problem list		
					ASTM notes that as with results, the CCR supports a snapshot of pertinent vital signs (which are technically a set of 'results').		
	Orders for additional consultative or educational services	HL7		Source?	HL7 notes that orders for consultative and educational services can be supported in HL7 v2.x and v3, however these are not commonly implemented. At least, not to the extent of the other information indicated for Medical History. Incorporation depends on ability of participating applications.		12+
					ASTM CCR in its 'Plan of Care' section supports all outstanding orders and requests for services. This provides prescribers with a core knowledge about what follow-up the patient is set for, and allows them to define what follow-up is needed (INR, therapeutic drug levels, cultures, vital signs monitoring, blood sugar, imaging studies, and the like).		

Data Element Terminology	Detail	Existing Terminology	Extent in Use	Terminology Gaps and Limitations Identified by Testifiers	Summary of Responses on How Gaps and Limitations may be Addressed	Address in: Near Term	Address in: Long Term
Terminologies (Code, Classification, and Vocabulary Dimensions to achieve consistency with the Structured Product Label (SPL) and other standrds within the CHI/NHII)							
Packaged drug product				Will each terminology be available in the UMLS in time for the demo? Will the terminologies be mapped to the DKBs in time for the demo?	NCPDP notes for all drug-related rows: The demonstration could function in the current environment where the prescriber chooses the drug information and transmits the information to the pharmacy. The pharmacy would continue to use NDC/UPC/HRI as applicable. Specific needs should be identified as part of MMA so that there is a clear course of action for the conversion/mapping to any new code sets. What is intended to be the outcome of the conversion/mapping? Which entity should convert/map to what? What business need is it addressing? What is the ROI/benefit? Who benefits? How to fund modifications? Will that entity benefit?		
					HL7 notes for all drug-related rows: it can support, or will be able to support, these terminologies within the structure of the HL7 messages, but we cannot address their inclusion in UMLS or mapping to/between DKB vendors	X	
					FDB and Medi-Span/WK Health note that DKB vendors have comprehensive databases of NDC, UPC, and HRIs in used and tested and should continue to be source for this timely and comprehensive content		
					SureScripts does not see a need for packaged drug product, clinical drug, active ingredient, non-proprietary drug product, proprietary drug product, chemical structure, drug class, mechanism of action, physiologic effect, therapeutic intent, clinical kinetics, drug component, or special ingredient information to be transmitted in the e-Rx environement		
		NDC	Used w/third party		FDA notes this is available now for most prescription drugs. NLM notes that what is available from FDA is in UMLS	Ltd	3-4 yrs
		UPC	Used in absence of NDC		NLM notes that UPCs are an uncontrolled terminology - no source for inclusion in UMLS		
		HRI	Used for devices incl in NDC from '70s		FDA reports it is considering development of processes similar to drugs for certain medical devices and supplies	No	??
Clinical drug		RxNorm			*See statement on RxNorm from NLM*		
					ASTM believes a correct and universally supported drug naming convention is needed at the generic drug name level and supported across EHRs, e-Rx, and DKBs.		
					NCPDP requests analysis of which functions of RxNorm will be best used in which functions of e-prescribing.		
					Medi-Span/WKHealth's mapping of RxNorm SCD to Medi-Span's Generic Product Identifier (GPI) will be available from Medi-Span in 2005; Medi-Span is automating the process of providing the Medi-Span's GPPC-5 concept to NLM for inclusion in the Metathesaurus for UMLS distribution	X	
					FDB anticipates continued use of FDB drug concept identifiers within POC prescriber and order fulfillment (pharmacy) applications. FDB is currently analyzing RxNorm with intent of publising cross-reference links to various RxNorm terminology types (TTY) to support interoperability applications. UMLS currently does not publosh a link between Semantic Branded Drug and NDC, and without this link, end-user navigation to SPLcontent will be dependent on DKB-maintained links.		

Data Element Terminology	Detail	Existing Terminology	Extent in Use	Terminology Gaps and Limitations Identified by Testifiers	Summary of Responses on How Gaps and Limitations may be Addressed	Address in: Near Term	Address in: Long Term
Active ingredient		FDA Unique	Not used		FDA is implementing system for registering	Yes	
					NLM notes that Structural Unique Identifiers will be in UMLS		
					Medi-Span/WKHealth is willing to map appropriate Medi-Span concepts to FDA's UNII once the term is published and available from FDA		X
					FDB notes that FDA unique ingredient code has yet to be published. FDB provides active ingredient information for pharmaceutical formulations, and will most likely publish links to RxNorm ingredients (TTY=IN) and ultimately FDA unique ingredient code once publishing workflow processes have been estabolished with NLM and internal cross-reference maintenance systems have been tested		
Non-proprietary drug product (active incredients, strength, manufactured dosage form)		From vendors			FDB and Medi-Span/WKHelath note that representation of ingredients, strength, and manufactured dosage form is currently available to customers based on info gathered from manufacturers		
		New from FDA?			FDA notes that changes needed to regulations and systems implemented to develop this identifier. NLM notes unsure of what this is.	No	3-4 yrs
					Medi-Span/WKHealth is willing to map appropriate Medi-Span concepts to FDA's concepts, where and when appropriate, once the FDA concepts are published and available from FDA		X
					FDB notes that assuming SPL content is published on a timely basis using tagged links to standard terminology and is made available to FDB prior to product launch, FDB could use the SPL to import data directly into internal database structures. This would improve our data collection process and would facilitate the linkage of FDB identifiers directly to SPL content. However, implementation and testing will be a significant undertaking and cannot begin until a significant number of SPLs have been published.		
Proprietary drug product (active ingredients, strength, manufactured dosage form, inactive ingredients and appearance)		FDA (labeler and product code from NDC)			FDA notes issues similar to NDC. Available now for many prescription drugs. Changes needed to regulations and systems implemented to fix issues with this identifier.	Ltd	3-4 yrs
					NLM notes that to the extent the NDC code is available from FDA, it will be in UMLS		
					Medi-Span/WKHealth clarifies that today, the Labeler and product portions of the NDC are not a stable identifier of a drug product; FDA is working on a stable, separate identifier for this concept; Once the FDA concept is published and available from the FDA or NLM, Medi-Span/WKHealth will incorporate the concept into our drugfile offerings.		X
					FDB's publication of NDC-UPC-HRI is currently based upon information gathered directly from manufacturers. Comprehensive and timely publishing of this information by the FDA could streamline FDB's procedures.		
Chemical structure		NDF-RT	In development		NLM notes this is in UMLS.		
					VA reports that NDF-RT uses a hierarchy of more than 5,000 chemical structure classes seeded from MeSH to identify drug ingredients. NDF-RT also includes links to 1176 FDA-generated UNII codes. NDF-RT depends on updates to these two outside databases and a periodic refresh process to maintain and expand these chemical structure concepts. Need to further develop pilot processes to (semi-) automatically update these links.		
					Medi-Span/WKHealth is willing to map appropriate Medi-Span concepts to VA NDF-RT's concepts, where and when appropriate, once the VA NDF-RT concepts are published and available from the VA. FDB sees the value in use of standardized chemical structures within the SPL.		X

Data Element Terminology	Detail	Existing Terminology	Extent in Use	Terminology Gaps and Limitations Identified by Testifiers	Summary of Responses on How Gaps and Limitations may be Addressed	Address in: Near Term	Address in: Long Term
Drug class		NDF-RT	In development		FDA is considering addition to SPL for drug products	No	Poss 3-4 yrs
					NLM notes this is in UMLS.		
					VA reports that NDF-RT uses drug class names from the VA National Drug File. There are 494 of these drug classes. The VA Enterprise Reference Terminology software environment allows users to add and manage additional local classes. Need to address single-vs-multiple-inheritance questions for harmony with existing applications.		
					ASTM believes this needs to be standardized and supported across EHRs, e-Rx, and DKBs.		
					Medi-Span/WKHealth is willing to map appropriate Medi-Span concepts to VA NDF-RT's Therapeutic Class concepts, where and when appropriate, once the VA NDF-RT concepts are published and available from the VA; Note: if the VA's Drug Classification is identified as the Therapeutic Classification for MMA Prescription Drug Programs, Medi-Span/WKHealth will provide a mapping from drug concepts to the classification in the "near term". If this is not the classification chosen for the MMA Prescription Drug Programs, Medi-Span/WKHealth will provide a mapping from drug concepts to the classification in the "long term".	X	X
					FDB currently provides therapeutic classifications that have become integral to many customer systems. We are unsure as to the broad market value of NDF-RT drug classes outside of the VA in light of proposed USP therapeutic class development.		
		USP	?		FDB reports this is unknown. USP plans a public session on 8/27/04 to discuss the topic. Ongoing timely maintenance, linkage to the NDC and publication process remain open issues.		
					Medi-Span/WKHealth is willing to map appropriate Medi-Span concepts to USP's Therapeutic Class concepts, where and when appropriate, once the USP's classification is published and available from the USP; Note: if the USP's Classification is identified as the Therapeutic Classification for MMA Prescription Drug Programs, Medi-Span/WKHealth will provide a mapping from drug concepts to the classification in the "near term". If this is not the classification chosen for the MMA Prescription Drug Programs, Medi-Span/WKHealth will provide a	X	X
					NLM asks when USP drug class will be available		
Mechanism of action		NDF-RT	In development		FDA is considering addition to SPL for drug products	No	Poss 3-4 yrs
					NLM notes this is in UMLS.		
					Va reports that NDF-RT uses a hierarchy of more than 250 mechanism of action concepts seeded from MeSH and further developed by subject matter experts to characterize drugs. Further development of this hierarchy will depend on advances in drug therapy and newly identified use cases.		
					Medi-Span/WKHealth is willing to map/code appropriate Medi-Span concepts **(mechanism of action, physiologic effect, therapeutic intent, clinical kinetics)** to VA NDF-RT's concepts, where and when appropriate, once the VA NDF-RT concepts are published and available from the VA; Clarification - is this within the scope of MMA? FDB notes that ongoing timely maintenance, linkage to the NDC and publication process remain open issues for these concepts.		X
Physiologic effect		NDF-RT	In development		VA reports that NDF-RT uses a hierarchy of nearly 1,700 physiologic effects concepts to characterize drugs. Originally seeded from MeSH and extensively developed by subject matter experts, these concepts can be expended or changed to meet local needs or to respond to advances in science and practice. Need additional modeling to address formulation-specific effects and synergistic effects of combination products.		

Data Element Terminology	Detail	Existing Terminology	Extent in Use	Terminology Gaps and Limitations Identified by Testifiers	Summary of Responses on How Gaps and Limitations may be Addressed	Address in: Near Term	Address in: Long Term
Therapeutic intent		NDF-RT	In development		FDA is considering providing indications for SPL for drug products	No	Poss 3-4 yrs
					VA reports that NDF-RT uses a hierarchy of more than 4,000 disease and disorder concepts to characterize the therapeutic intent of medication use. Based on MeSH and refined by subject matter experts, this hierarchy has been considered for replacement or augmentation with pointers to synonymous SNOMED concepts in order to take advantage of the richness of SNOMED hierarchies. Need additional modeling to accommodate formulation-specific uses. Need to develop processes (perhaps leveraging commercial KB vendor cooperation with NLM) to to access and possibly ntegrate outside knowledge into these links.		
					NLM notes this is in UMLS.		
Clinical kinetics		NDF-RT	In development		FDA is considering providing indications for SPL for drug products		
					VA reports that NDF-RT includes a set of semantic links to connect drugs to their pharmacokinetic properties. A prototype set of kinetic concepts (50+ concepts) and relationships (27 relationships) has been built for further evaluation.		
					NLM notes this is in UMLS.		
Drug component		RxNorm	Not used		FDB notes that the semantic clinical drug component (TTY = SCDC) does not currently include the salt form of the ingredient (represents ingredient plus strength). Appropriate linkage of the SCDC to SPL information will require specificity to		
					Medi-Span/WKHealth's mapping of RxNorm SCDC to Medi-Span's drug concepts, where and when appropriate, will be made available from Medi-Span		
					NLM notes this is in UMLS.		
Dosage form		RxNorm	Not used		FDA notes that manufactured dosage form is in SPL	Yes	
					NLM notes this is in UMLS.		
					NCPDP notes there is an existing code sets in X12 for Drug Form (DE 1330) which NCPDP SCRIPT		
					FDB notes that RxNorm dosage form level of abstraction is intended to support order entry applications, not the representation of the "manufactured dosage form." SPL is expected to publish the FDA manufactured dosage form. One RxNorm dosage form will span one-to-many FDA manufactured dosage forms.		
					Medi-Span/WKHealth's mapping of Dosage forms used within RxNorm to Medi-Span's concepts, where and when appropriate, will be made available from Medi-Span; Clarification - I thought HL7 was the owner of the dosage form terminology and it was availble from the ULMS but was not an "RxNorm" concept?		
					ASTM believes this needs to be standardized and supported across EHRs, e-Rx, and DKBs.		

Data Element Terminology	Detail	Existing Terminology	Extent in Use	Terminology Gaps and Limitations Identified by Testifiers	Summary of Responses on How Gaps and Limitations may be Addressed	Address in: Near Term	Address in: Long Term
Special ingredient information/ modifiers (e.g., Lactose free, wo/alcohol, flavors)		DailyMed	In development		FDA is considering addition to SPL for drug products	No	Poss in future
					NLM reports Daily Med is envisioned to be a source of a large body of information relating to drug products, with its core being the RxNorm name. It will include SPL and information about drugs in NDF-RT. It will be available as a downloadable file and Internet browsable database. Although the RxNorm, NDF-RT and FDA names and codes will be pulled from or added to the UMLS Metathesaurus, most Daily Med information will not be terminological, so it will not appear in the UMLS.	After FDA begins transmitting SPL to NLM, Q3 2005	
					Medi-Span/WKHealth notes that when available from the manufacturer, it currently supplies this information in itsdrugfiles; a proprietary code set is used since there is not a national standard for this type of information; Clarification - the DailyMed is a NLM communication vehicle for new drug information from the FDA. Will it include these type of information? In a textual or codified format?		
					FDB notes it would be very useful for excipient ingredient information to be published with FDA unique ingredient codes and "freeness" qualifiers to support the programmatic use of this information.		
					SureScripts notes that universally accepted dosage form codes need to be developed in the near term.		
					Pfizer notes this needs to be included in the message between prescriber and dispenser and that standard vocabularies need to be developed, perhaps through the SPL. Once done and messaging requiremens articulated, this could be included in NCPDP SCRIPT for transmission to dispenser.		
Compliance packaging form		RxNorm			FDA notes package type included in SPL	Yes	
					HL7 notes this could be included as an attribute of the medication ordered. Need additional information to assess how this can be supported (or is supported) in HL7 v2.x and v3)		Unkn
					NACDS notes that the compliance packaging form should be based on objective criteria for the drug product, not on the NDC manufacturer level and this value should be tested in the 2006 pilot.		
					Medi-Span/WKHealth currently supplies this information in our drugfiles; a proprietary code set is used since there is not a national standard for this type of information.		
					Pfizer notes that NLM has indicated they are including compliance packaging in RxNorm, which could be handled as a differentiating features (see Special Ingredients).		

Data Element Terminology	Detail	Existing Terminology	Extent in Use	Terminology Gaps and Limitations Identified by Testifiers	Summary of Responses on How Gaps and Limitations may be Addressed	Address in: Near Term	Address in: Long Term
Drug delivery devices		RxNorm			FDA notes that depending on the devices, this may be included in the SPL		
					Medi-Span/WKHealth currently supplies this information in our drugfiles; a proprietary code set is used since there is not a national standard for this type of information. If a national code set is identified, Medi-Span/WKHealth will map/code to this codeset. Clarification - where in RxNorm is this information available? It is not a termtype of RxNorm.		X
Units of measure		ISO 2988 ANSI X3.50			FDA notes units of measure in SPL	Yes	
					NCPDP notes there is an existing code sets in X12 for Unit of Measure (DE 355) which NCPDP SCRIPT uses.		
					HL7 identified two standards, and notes that there are inconsistencies between these standards, and additional customary (non-standard) UOM.		
					Medi-Span/WKHealth currently supplies this information in our drugfiles; a proprietary code set is used since there is not a national standard for this type of information.		
					SureScripts notes that a standardized method of transmitting compliance packaging form needs to be developed and tested in pilots		
					ASTM believes this needs to be standardized and supported across EHRs, e-Rx, and DKBs.		
SIG (instructions for use)	Warnings and cautions (see below)	None	FDA internal standards	Are there issues with minimum data set needed plus accommodate free text?	Pfizer suggests the SPL could be used as a source for this info if common dosing regimens were included in a structured format. NCPDP is investigating this and may be completed in time for pilots	X	
					ASTM notes that the CCR (and SureScripts) support a full data set that supports administration of a medication in an office, patient's home (home health), the hospital (inpatient or a prescription on discharge), in a long term care facility, or as a prescription or refill. All components are fully supported and tagged by CCR		
					Medi-Span/WKHealth recommends for SIG information overall that for the first phase of e-rx recommendations and the demonstration project that a textual SIG string be used. If a portion of the SIG needs to be codified for the demonstration project, we recommend just the concepts of frequency, dose quantity, and duration with their respective units of measure be included. Medi-Span/WKHealth currently supplies all detail except administration site and rates of infusion in its drugfiles; a proprietary code set is used since there is not a national standard for these types of information.		
					FDB notes SIG information and components currently available from FDB in proprietary format.		
					HL7 can include as free-text instruction to patient. Encoding would require additional characterization in order to evaluate impact. Suggests that some thought should be given to what this exactly means: completely encoded terminology, structured text, free text with specific attributes coded, etc.		Unkn

Data Element Terminology	Detail	Existing Terminology	Extent in Use	Terminology Gaps and Limitations Identified by Testifiers	Summary of Responses on How Gaps and Limitations may be Addressed	Address in: Near Term	Address in: Long Term
					NCPDP notes that free text (what the prescriber chooses) must be allowed in any transaction. NCPDP Work Group 10 is currently addressing the SIG and its components.		
	Frequency		DKB proprietary		Hl7 v2.x and v3 can support as a specific attribute, but these are not necessary part of a construct that could be termed a "SIG".		
	Route		HL7 Drug order std supports, but not in wide		Hl7 v2.x and v3 can support as a specific attribute, but these are not necessary part of a construct that could be termed a "SIG".		
	Administration site				Hl7 v2.x and v3 can support as a specific attribute, but these are not necessary part of a construct that could be termed a "SIG".		
	Indication (e.g., PRN for pain)				Hl7 v2.x and v3 can support as a specific attribute, but these are not necessary part of a construct that could be termed a "SIG".		
	Medication modifiers (e.g., with/without food)				HL7 can include as free-text instruction to patient. Encoding would require additional characterization in order to evaluate impact.		
	Conditional frequencies (e.g., 1 hr before procedure)				Hl7 v2.x and v3 can support as a specific attribute, but these are not necessary part of a construct that could be termed a "SIG".		
	Rates of infusion				Hl7 v2.x and v3 can support as a specific attribute, but these are not necessary part of a construct that could be termed a "SIG".		
Structured Product Label	See FDA for 25 components of content	HL7 (SPL) in HL7 CDA	FDA new requirement	Does this need to be included in demo?	FDA is considering this addition to SPL for drug products. NACDS, Pfizer, SureScripts believe this should be included in pilot to demonstrate value. Since this data is apparently still under development, Medi-Span/WK Health recommends that this not be included in the demo. In the long term, Medi-Span has interest in mapping to the SPL	No	Beg 2006
					HL7 does not believe a demonstration of SPL is essential to the function of ePrescribing. If it can reasonably be accomodated, it should be included (that is, if there are vendors that can brirng this in time for the demo, it should be included.)		
Devices, DME & supplies		NDC	When available	Does this need to be included in demo?	FDB notes items eligible for Medicare payment should be made available in the demo with links to administrative code set identifiers required for claims processing.		
					HL7 notes any "orderable" item can be included in an HL7 v2.x or v3 message. Unless there is a mandate to include DME, etc in the demo, it might be better to focus on medications and include DME if it can be reasonable accomodated.		
					NCPDP notes that some supplies are covered in Medicare prescription drug program, so they can be included as part of the current e-prescribing environment.		
		UPC	When NDC is not available				
		HRI	When NDC is not available		FDA is considering evaluation handling similar to NDC for drug products	No	?

Data Element Terminology	Detail	Existing Terminology	Extent in Use	Terminology Gaps and Limitations Identified by Testifiers	Summary of Responses on How Gaps and Limitations may be Addressed	Address in: Near Term	Address in: Long Term
Medical history	Medical history (see below)			Does this need to be included in demo?	ASTM believes this needs to be supported in demo and is fully supported by CCR. NACDS and SureScripts believe this needs to be included in demo to demonstrate value		
					HL7 notes that on a medication history, dispensed medications would always have an NDC number. This would simplify the terminology aspect and may suggest that medication history should be included in the demo		
					FDB notes that depending upon the scope of HHS e-prescribing requirements, medical history must be exchanged. The purpose of the demonstration project is to establish the feasibility and market acceptance of proposed requirements. All proposed HHS e-prescribed requirements should be validated in demonstration projects prior to implementing regulations that mandate use within production systems. FDB is prepared to provide links to proprietary content		
	Complaint	SNOMED	Recommended by NCVHS (or HIPAA code set)		Medi-Span/WKHealth is currently mapping this information into our drug files and will be available by Jan 2005. HL7 notes that each element can be supported by HL7 v2.x or v3 messages as an associated observation, and believes medical history should be included in demo if it can be reasonably accomodated by application vendors	X	
	Problem List	SNOMED			Medi-Span/WKHealth is currently mapping this information into our drug files and will be available by Jan 2005	X	
	Diagnosis	SNOMED, ICD			Medi-Span/WKHealth is currently mapping SNOMED to our drug files and will be available by Jan 2005. Medi-Span currently provides ICD-9 mappings to the Medi-Span drug files.	X	
	Lab Results	LOINC			Medi-Span/WKHealth currently maps to the LOINC terminology.	X	
	Clinical Findings	SNOMED			Medi-Span/WKHealth is currently mapping this information into our drug files and will be available by Jan 2005	X	
Medication history	Medication history	NDC, RxNorm, NDF-RT		Does this need to be included in demo?	ASTM believes this needs to be supported in demo and is fully supported by CCR. FDB believes this needs to be included in demo as DUR cannot occur without it. NACDS and SureScripts believe this needs to be included in demo to demonstrate value. Rx Benefits Coalition notes this should be included in demo, but also notes that NDC is the identifier sent on medication history since it represents the dispensed medication.		
					NCPDP notes that any new databases/terminologies will not exist in a historical reference, unless the demonstration is manufactured? CMS to work with current implementers of medication history to demonstrate what is available now.		
					HL7 notes that on a medication history, dispensed medications would always have an NDC number. This would simplify the terminology aspect and may suggest that medication history should be included in the demo		
					Medi-Span/WKHealth notes NDC is currently available. While Medi-Span/WKHealth's mapping of RxNorm SCD to Medi-Span's Generic Product Identifier (GPI) will be available from Medi-Span by Jan 2005, we recommend that for the demonstration project include the NDC and/or the RxNorm as the drug identifier.	X	

Data Element Terminology	Detail	Existing Terminology	Extent in Use	Terminology Gaps and Limitations Identified by Testifiers	Summary of Responses on How Gaps and Limitations may be Addressed	Address in:	
						Near Term	Long Term
Manifestations of ADE		Medra		Does this need to be included in demo?	FDB notes that Medra is proprietary and has not been deemed a "standard" terminology for PMRI. SureScripts believes this should be included in pilots. Medi-Span/WKHealth believes this is outside the scope of MMA and should not be included in the demo.		
Indications (Dx-Drug relationships)				Does this need to be included in demo?	ASTM believes this needs to be supported in demo and is fully supported by CCR. FDB notes it provides proprietary indications content. NACDS and SureScripts believe it should be included in pilot to demonstrate value		
					HL7 notes this can be supported by HL7 v2.x or v3 messages and should be included in demo if available from application vendors.		
					NCPDP notes that for all the DUR functions noted below - If a standard vocabulary is determined, the SCRIPT Standard can incorporate. (The pharmacy and payer performs DUR checking in the claims environment every day.)		
DUE fields in SCRIPT	Based on code lists used in NCPDP SCRIPT and Telecommunication Standards	Yes	For claims, extensively used by pharmacies and payers in claims processing.		SCRIPT has the ability to share the drug prescribed and the drug dispensed. It can also list alternate drugs.		
· Drug Coverage Status Code, identifying the coverage status of the prescribed drug.	Example values: Preferred; Approved; Prior Authorization Required; Non Formulary; Not Reimbursed; Differential Co-Pay; Step Therapy Required; Unknown						
· DUE Reason For Service Code, for the type of conflict detected	Same codes for pharmacy billing processes. Example values: Adverse Drug Reaction; Additive Toxicity; Drug-Allergy; Drug-Food Interaction; Tobacco Use; Apparent Drug Misuse; Lactation/Nursing Interaction; Side Effect						
· DUE Professional Service Code, for identifying intervention	Same codes for pharmacy billing processes. Example values:						
· DUE Result Of Service Code, for action taken in response to a conflict.	Same codes for pharmacy billing processes. Example values: Filled As Is; False Positive; Filled Prescription As Is; Filled, With Different Dose; Filled, With Different Directions; Filled, With Different Drug; Filled, With Different Quantity; Brand-to-Generic Change; Rx-to-OTC Change						

Data Element Terminology	Detail	Existing Terminology	Extent in Use	Terminology Gaps and Limitations Identified by Testifiers	Summary of Responses on How Gaps and Limitations may be Addressed	Address in: Near Term	Address in: Long Term
· DUE Co-Agent ID, DUE Co-Agent ID Qualifier, Identifies the co-existing agent contributing to the DUR event (drug or disease) conflicting with the prescribed drug.	Same codes for pharmacy billing processes. Example values: NDC, UPC, HRI, HCPCS, GPI, GCN, GFC, GM						
Decision rationale				Does this need to be included in demo?	Medi-Span/WKHealth believes this should not be included in demo. HL7 suggests this n ot be included in demo as a number of questions need to be addressed, such as how does one describe "decision rationale."		
Drug-Allergy groups		World Allergy Organization	Ongoing research	Does this need to be included in demo?	For interoperability purposes, FDB is prepared to link to SNOMED-CT medication allergy class identifiers organized within the "substance" domain (published in the "core" product). We are unfamiliar with terminology published by the World Allergy Organization. SNOMED-CT has the advantage of already being deemed as "standard terminology".		
		SNOMED			Medi-Span/WKHealth currently supplies an allergy identifier in our drugfiles; a proprietary code set is used since there is not a national standard for this type of information. If a national code set is identified, Medi-Span/WKHealth will incorporate, as appropriate, in its product.		X
					NACDS and SureScripts believe it should be included in pilot to demonstrate value		
					HL7 notes this may be part of the user interface (for both prescriber and dispenser) but would not appear to be necessary information sent in a message.		
					ASTM believes this needs to be standardized and supported across EHRs, e-Rx, and DKBs as a critical safety issue. NACDS and SureScripts believe it should be included in pilot to demonstrate value		
Drug interaction groups					FDA is considering addition to SPL for drug products	No	Years
					HL7 notes this may be part of the user interface (for both prescriber and dispenser) but would not appear to be necessary information sent in a message.		
					Medi-Span/WKHealth recommends that a qualifier/type code be included in a DUR result message, but do not recommend that a value for each drug-drug interaction be included or recommend by the committee; If this is only a qualifier, then we recommend that this be included in the demonstration project. Otherwise, we recommend this not be included in the demonstration project.		
	D-Drug			Does this need to be included in demo?	ASTM believes D-D, D-F, and D-L need to be standardized and supported across EHRs, e-Rx, and DKBs as a critical safety issue.		
	D-Food			Does this need to be included in demo?	FDB provides proprietary D-D, D-F, and D-L interference information.		
	D-Lab			Does this need to be included in demo?	NACDS and SureScripts believe it should be included in pilot to demonstrate value		

Important Related Issues and Possible Next Phase Issues for Investigation			
Important Related Issues	**Description**	**Associated Organizations/ Standards**	**Summary of Testimony**
Enhancing patient safety	Requirements for use of medical and medication history for decision support	Institute of Safe Medication Practices	NCPDP notes it is important to build criteria and test plans so that the information can be analyzed and improvements be measured. ASTM notes this is fully supported by CCR.
			SureScripts notes that the NCPDP SCRIPT supports passing dispensing information between prescriber and dispenser and should be tested in 2006 pilots.
			Pfizer notes many different entities possess different types of medication history. The pharmacy network in aggregate has the most complete set of prescription history - whether paid for through a PBM or with cash - and OTC purchase history, though it may be spread out between various chains and independent pharmacies. While the SCRIPT standard has messaging standards for communicating this information, there are no clear business rules or reimbursement mechanisms for its distribution to prescribers. Additionally, inpatient and hospital system medication history may reside in pharmacy systems based in HL7. The coordination of cross-mapping between HL7 and NCPDP SCRIPT needs to occur in order to capture these data. Payers also have a significant set of records related to prescription information, but it is not ultimately as comprehensive as the data contained in the pharmacy network. By promulgating standards that ensure that the most complete medical and medication history is available to prescribers, patient safety will be enhanced. This issue needs to be thoroughly addressed in pilots.
			Rx Benefits Coalition and RxHub note that there should be a requirement to use medical and medication history for decision support, like a general requirement to use e-prescribing, would enhance patient safety.
	Enhancing patient compliance with medication through enhanced information about prescription filling		NCPDP notes that the Fill Notification messages facilitate the electronic transfer of information. This will not enhance patient compliance (you cannot force the patient to take the medication), but rather provide the prescriber with information with which to discuss further with the patient.
			Pfizer strongly supports the use of electronic prescribing systems to improve and enhance patient compliance with prescription drug regimens through monitoring prescription filling information and communicating such information to patients and physicians. Mechanisms for support of the transmission of this information between the prescriber and dispenser should be devised that allow manufacturers and others to cover the costs of these transactions.
			Rx Benefits Coalition and RxHub believe medication history must be as complete as possible, including from multiple prescribers, pharmacies, and payers.
			NACDS notes this should be tested in 2006 pilots.
	Requirement to support interactive prior authorization		Rx Benefits Coalition and RxHub believe interactive prior authorization is not practical under any existing standards. It would be very difficult to develop a standard flexible enough to address all of the potential issues arising in a prior authorization. Moreover, implementing such a standard would be a burden disproportionate to the small number of drugs that are subject to prior authorization requirements.
			Pfizer believes standards for delivering a structured formulary and structured prior authorization are greatly needed to ensure that the prior authorization process itself is not used as an inhibitor of patient and physician choice and thereby restrict the efficient delivery of quality care. The physician should be able to use an electronic prescribing tool to seamlessly prescribe the drug, be informed of prior authorization requirements, be informed when those requirements are met, and transmit the authorization to the pharmacy. As Pfizer testified in July, we ask that NCVHS recommend that these issues be addressed by the appropriate SDOs and tested in demonstration projects.
			SureScripts is in favor of physicians and pharmacies having interactive access to prior authorization. Before implementing, clear requirements by payers will have to be made available.
			NACDS notes prior authorization should be able to occur between the prescriber and payer without the need for transmitting this information through community pharmacies.
Improving quality	Ensuring complete and accurate instructions to patients (SIGs)		HL7 notes "standardization of the SIG" is a long-standing concern in a number of organizations. NCPDP and HL7 have recently revived efforts and are working to coordinate our activities. (personal comment - it may be time to take a step back and think about what we mean by "standarizing the SIG". Are we really trying to encode the SIG, or are we trying structure the text of a SIG. A more conceptual approach may be helpful)

Important Related Issues and Possible Next Phase Issues for Investigation			
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			NCPDP notes that pharmacists today make sure that complete and accurate instructions are given to patients. Sharing electronic text SIG will decrease the call backs to interpret handwriting. Pharmacists still may call to clarify that the instructions if something does not appear correct.
			SureScripts notes the completeness and accuracy of instructions to patients is under the control of pharmacists and the pharmacy software vendors who serve them. These parties will have to be brought into this discussion to achieve these quality improvement goals.
			Pfizer supports the development of a structured sig to enhance patient care and would urge cooperation among SDOs involved in this process in order to construct a workable structured sig. We would encourage HHS to examine the use of the FDA's Structured Product Label as a possible source for common dosing regimens for drugs that could be incorporated into a structured sig.
			Rx Benefits Coalition and RxHub believe coding and free-form text should coexist for SIG.
			ASTM notes this is fully supported by CCR - the fully tagged "sig" can be converted from physician terminology to patient terminology through XSLT translation using the CCR. This cannot be supported by free text "sig."
	Ability to capture medication errors and ADE		NCPDP notes that pharmacy systems and payer systems are performing DUR every day and stopping medication errors and ADE. The electronic messages will not stop a patient who chooses not to take a needed medicine or takes it incorrectly and ends up in the emergency room. But obviously there is room for improvement in different aspects of healthcare.
			NACDS notes this would appear to be outside the scope of e-Rx.
Policies for standards	Providing safe harbor		Pfizer notes the safe harbor standards currently make no mention of manufacturers as having safe harbor for supporting e-prescribing programs. Payers and providers have a financial stake in the prescriber's decision-making process, as do manufacturers. We would like to see clarity in the safe harbor provisions that would treat all entities with a financial stake in the prescriber's decision-making process in a similar fashion so that manufacturers would have an opportunity to appropriately support e-prescribing initiatives in the future.
	Preserving provider/patient choice		SureScripts supports prescribers having entire formulary and patients having a complete list of pharmacies.
			Pfizer believes electronic prescribing policy standards should provide that e-prescribing technologies should not be used for the purpose of biasing and steering physicians to drugs preferred by any third party. The point of prescribing should be considered a "zone of autonomy", where the prescriber is protected from influence by outside interests. The prescriber should be able to fully control how medication lists are presented and sorted and what sorts of information is available at the time of prescribing. In particular, prescribers should be able to view with equal ease all necessary information about drugs that are preferred on-formulary, non-preferred on-formulary, and off-formulary, without having to “click” through multiple screens or other burdensome steps. The information provided to the prescriber should be fact-based and transparent, and should identify the source of the information. Any incentive payments given to technology vendors to display information in a particular way should be fully disclosed to the physician or pharmacist and any advertisements clearly labeled. Finally, electronic prescribing technology should include relevant drug information that would permit the physician to address the unique characteristics (allergies, co-morbidities, contraindications, religious and social preferences, etc) of her patients. Electronic prescribing standards should be established to catalogue and communicate these differentiating features. In this regard, one solution may be to adapt the FDA’s Structured Product Labeling initiative as the source of the content for these features and then modify relevant portions of NCPDP Script and HL7 to transmit this information.
	Free of commercial bias		Rx Benefits Coalition and RxHub note that commercial bias is not an issue that can be effectively addressed by the MMA standards. Defining the distinction between clinically relevant information and "commercially biased" information is too difficult. Physicians and pharmacists have rejected and will reject software that is commercially biased and it is unlikely commercially biased approaches will succeed.

Important Related Issues and Possible Next Phase Issues for Investigation			
Important Related Issues	**Description**	**Associated Organizations/ Standards**	**Summary of Testimony**
			Pfizer notes that the MMA requires electronic prescribing standards to "allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems." PBMs, health plans, manufacturers and other entities with a financial interest must not be allowed to interfere, either directly or through third parties, with physicians' clinical decisions (in particular during the act of prescribing a particular drug or choosing a particular pharmacy for dispensing the drug) through the use of extraneous electronic messages. No commercial messages should be allowed that are directly tied to health care provider (physician or pharmacist) selections of medication therapy or choice of dispensing pharmacy. Unfortunately, no definition of inappropriate messaging exists. The Committee should recommend that HHS address these gaps by developing policy standards that provide an explicit definition of what constitutes inappropriate messaging and clearly define what specific types of messages are prohibited. Pfizer recommends that inappropriate messaging be defined as an effort by a third party – payers, PBMs, pharmacies, or manufacturers – to influence the prescribing decision at the point of care. While the standards should not restrict the neutral presentation of formulary information, messaging should not be allowed that would attempt to influence a physician's decision for commercial reasons, either at the outset of the prescribing decision or after the decision has been made. Additionally, the standards should provide that electronic prescriptions should be transmitted directly to pharmacies without interference from third-party payers or PBMs who have a vested financial interest in what medication is being prescribed and where the prescription is dispensed.
	Ensure consistency with CHI standards		
Ensure incorporation of decision support in E-Rx	Exchange standards for decision support algorithms need to be developed, that	FDA Structured Product Label is a base for decision support and needs to be ready for pilot	HL7 Arden Syntax and other standards may be of interest.
Transmission method		Many, incl XML	HL7 notes multiple transmission technologies supported by HL7 v2.x and v3. v3 is primarily rendered in XML. An XML format for v2.x is available.
			NCPDP notes this should not be constrained. Dial up, leased line, frame relay, internet are all various communication methods. The business need and timing should determine which method. XML is not a transmission method, but rather a messaging?
			NACDS and SureScripts notes that transmission method should be agreed to by trading partners.
			NABP notes that once a prescriber has transmitted an electronic prescription, no intervening entity may alter the prescription information. Any altering by an intermediary of a prescribed drug, strength, quantity, allowed refills, or directions would adversely affect patient safety and is in direct conflict with state laws that were established to ensure the integrity of the prescribing process.
			SureScripts notes that examination of a transmission (e.g., to ensure inclusion of all required content, check format for pharmacy computer recognition) and retention of a confidential audit copy for technical processing purposes does not change the clinical content of the prescription and strictly maintains confidentiality, but depending on the specific regulations and their interpretation, these activities have been deemed to be in violation of some state laws; hence recommends that the focus should be on types of activities that should not be allowed.
Conformance testing of e-Rx standards			HL7 has establish a Conformance documentation standard, additional information can be supplied if desired by the committee
			Pfizer supports the development of e-prescribing conformance testing of vendors to ensure that their applications and business practices conform to the standards established for e-prescribing under MMA. This certification process should cover both the technical requirements of an application and the policy standards we have discussed in our previous testimony and in this document.

Important Related Issues and Possible Next Phase Issues for Investigation			
Important Related Issues	**Description**	**Associated Organizations/ Standards**	**Summary of Testimony**
Provide privacy protections		HIPAA	ASTM notes CCR supports data element level confidentiality
			Rx Benefits Coalition and RxHub note that HIPAA standards as currently applied should continue to protect patient privacy and with respect to e-Rx.
Provide security controls	Identify source and owner of data	HIPAA	ASTM notes CCR supports "source" links for all data elements
	Back up and disaster recovery	HIPAA	
	Change password	NCPDP SCRIPT	
	Authentication	To be addressed after Sept. 2004 under e-signature	ASTM notes CCR supports full digital signature capabiliteis
			Rx Benefits Coalition and RxHub note that authentication should take into account internal systems checks as well as progress in electronic signatures. Several electronic signature initiatives are underway and an additional standard at this time would be unproductive.
			NACDS notes that NCPDP JWG 11/12 is currently addressing e-signature.
Functional requirements for e-prescribing	Need to identify e-prescribing functions to support possible incentives	HL7 EHR DSTU source	HL7 notes this is ongoing work and would appreciate any comments, suggestions and information on related activities/efforts.
			NACDS notes pharmacies should be eligible for any incentives offered to other health care providers.
E-prescribing needs to support evidence-based clinical decision making		AMA Physician Information and Education Resource (PIER)	HL7 notes that evidenced-based clinical decision making is, functionally, a component of the user interface and front-end application. However, support for this required information that may be transported in messages of various formats. Some of these messages may not be part of the "general understanding" of ePrescribing (e.g., Lab results).
			Pfizer notes that evidence used to support clinical decision making should be under the control of the prescriber and should be clearly sourced in terms of its origin and any entity that supports its availability within the e-prescribing environment. Continuing Medical Education uses a model like this to ensure a separation of commercial bias from education.
Development of standards for e-prescribing should consider potential work flow changes	Business case		Rx Benefits Coalition and RxHub notes technology and workflow should be coordinated. Consequently, standards that are in use today should be adopted in preference to new standards that have not been tested and have not received adequate stakeholder input.
	Efficiency		
	Roles		

Important Related Issues and Possible Next Phase Issues for Investigation			
Important Related Issues	**Description**	**Associated Organizations/ Standards**	**Summary of Testimony**
Federal preemption of State e-prescribing regulations is necessary	Prescription format	NABP Model Act	NABP notes virtually every state has the same requirements regarding the prescription content: (1) full name and street address of the patient, (2) name, address, and DEA if required, (3) date of issuance, (4) name, strength, dosage form, and quantity of drug prescribed, (5) directions for use, (6) refills authorized, if any, (7) if a written prescription drug order, prescribing practioner's signature, (8) if an electronically transmitted prescription drug order, prescribing practitioner's electronic or digital signature, (9) if a hard copy prescription drug order generated from electronic media, prescribing practitioner's electronic or manual signature. For those with e-signatures, such prescription drug orders shall be applied to paper that utilizes security features that will ensure the prescription drug order is not subject to any form of copying and/or alteration.
			NABP notes an electronically transmitted prescription shall contain the following: (1) transmitter's phone number or any other suitable means to contact the transmitter for verbal and/or written confirmation, (2) time and date of transmission, (3) identrity of pharmacy intended to receive transmission, identity of transmitting agent, if authorized by prescriber, and (5) any other information required by state or federal law.
			Pfizer notes the MMA preempts all state laws that are contrary to, of otherwise restrict, the implementation of an electronic prescribing program. In implementing electronic prescribing standards, we urge the Committee to recommend that the Secretary provide clear guidance on state laws that would be preempted. Clarity is needed so that e-prescribing stakeholders can know with certainty the degree to which their conduct is governed by state law.
			Rx Benefits Coalition and RxHub notes that Federal preemption provides an opportunity break down restrictions that impede adoption of a multi-state system. Multiple format requirements, especially format requirements that assume paper prescriptions, should be standardized for use in e-prescribing systems that can be used nationwide.
			NACDS notes generally standardized from state to state, preemption not likely necessary.
			NABP Dispense as Written (DAW) requirements need to be addressed by technology. Drug product selection requirements in the states are outside the purview of the state boards of pharmacy and impose additions to the standard prescription format. These additions focus on the prescriber indicating whether a product can be substituted. The required terminology and signature format to comply with drug product selection requirements in the states is specific and more varied from state to state than the basic patient, medication, prescriber, pharmacist, and pharmacy information listed above.
	Record retention	State laws	NABP notes prescription retention requirements span from 2 years to 7 years depending on the state. Is there a correlation between the record keeping requirements in each state and the statute of limitation requirements for a person to file a medical malpractice lawsuit? NCVHS may want to take this into consideration when determining the record retention requirments.
			Rx Benefits Coalition and RxHub note that record retention requirements that require paper based records are an unnecessary cost in implementing e-prescribing. Likewise, multiple, different record retention requirements raise the cost of implementing e-prescribing. A nationwide standard for e-prescribing record retention would reduce unnecessary costs and promote adoption of e-prescribing.
			NACDS notes some states prohibit record retention, preemption necessary.
		DEA	NABP notes every inventory and other records required to be kept under this part shall be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration. [21CFR1304.04]

Important Related Issues and Possible Next Phase Issues for Investigation			
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	Signature requirements	NABP Model Act	NABP notes: electronic or digital signature
			Rx Benefits Coalition and RxHub note signature requirements vary from state to state and often do not reflect the current state of the health care industry in electronic signatures, which is still in its infancy. A nationwide standard for authentication would reduce the uncertainties in many states currently surrounding implementing signature requirements in electronic prescribing systems. However, a standard for authentication need not rely on electronic signatures as the only or even the primary means of authenticating prescriptions and other information.
			NACDS notes little standardization exists, broad preemptions likely needed.
		DEA	NABP notes DEA has not yet released their standard for e-transmission of controlled substances. The anticipated standards indicate that digital signature will most likely be required for the electronic transmission of controlled substances.
Inclusion of over-the-Counter Drugs		UPC	HL7 messages are not limited to prescription medications. As long as there is a means to specifically identify a product (e.g., UPC), then those products can be supported in an HL7 v2.x or v3 message.
			Rx Benefits Coalition and RxHub note including OTC drugs may be a good idea in the long term, but currently the OTC distribution process is too different from that for prescription drugs. It would be difficult, for example, to include OTC drugs in medication histories. This is not "low-hanging fruit".
Inclusion of complimentary therapies		Alternative Link, SNOMED, CPT	
ADE reporting by prescriber to other providers or to central repository		National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Taxonomy of Medication Errors	HL7 notes that there has been some work within HL7 v3 for an adverse event message. Futher development of this message will need to be coordinated with other organizations (NCC MERP is referenced in the Prescription Drug Benefit NPRM)
E-signature adoption	Will receive testimony after Sept. 2004		HL7 notes the technology employed for eSignature should be able to be supported with current HL7 v2.x and v3 data types, but the final standard will have to be reviewed. The usage of eSignature within the message must also be assessed. For example, is there only one signature (the prescriber) or could there be multiple signatures (co-signer).
			NACDS notes e-signature should carry n o more requirements than the national E-Sign law based on intent to be identified.
			Rx Benefits Coalition and RxHub note that authentication and e-signature are linked and should be addressed as a package.
			ASTM notes this was demonstrated for the CCR by Carnegie Mellon University, MISM CCR Project using public-domain authentication and digital signature algorithms.
Delay of the DEA to provide guidance on the e-Rx of controlled substances		DEA	Noted by Medi-Span/WKHealth
Long-Term Care			Research unique needs of this industry for electronic prescribing.
Controlled Substance prescriptions		DEA	Research into whether the electronic prescribing of controlled substances needs to be held to different rules (digital certificates etc) or whether the same "standards" as other prescriptions, with regulations/audits/etc performing the necessary controls? NPRM from DEA.