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October 27, 2006

Alisa Ray
Executive Director
Certification Commission for Healthcare Information Technology (CCHIT)
233 N. Michigan Avenue, 21st Floor
Chicago, IL 60601

Comments:

Proposed Functionality for 2007 Certification of Inpatient EHRs and Proposed Criteria for 2007 Certification of Inpatient Interoperability

Dear Ms. Ray:

The American Society of Health-System Pharmacists (ASHP) is pleased to respond to the Certification Commission for Healthcare Information Technology (CCHIT)'s Proposed Criteria for Inpatient Interoperability and Supplement to Roadmap. ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care agencies, and other components of health systems. ASHP has a long history of policy development with respect to the medication use system, appropriate use of technology, and the importance of interoperability throughout the inpatient, outpatient, and other continuum of care settings.

ASHP established an Ad Hoc Informatics Advisory Committee (participants attached) to develop the enclosed comments. Although the comment period for this draft was brief, we have none the less provided specific suggestions on a number of inpatient criteria with respect to functionality and interoperability. You will also find general comments on the criteria and several suggested additions within our comments.

As CCHIT finalizes its work, ASHP offers its expertise and welcomes further opportunities to provide additional information regarding our comments. I can be reached by telephone (301-664-8730) or email (dscheckelhoff@ashp.org).

Sincerely,

Douglas J. Scheckelhoff, M.S., R.Ph.
Director, Pharmacy Practice Sections

Executive Summary

ASHP Comments on
Proposed Functionality for 2007 Certification of Inpatient EHRs and Proposed Criteria for 2007 Certification of Inpatient Interoperability

The American Society of Health-System Pharmacists (ASHP) is pleased to respond to the Certification Commission for Healthcare Information Technology (CCHIT)'s Proposed Criteria for Inpatient Interoperability and Supplement to Roadmap. ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals and other organized health systems. We salute CCHIT for the outstanding work in developing criteria for ambulatory, inpatient and interoperability certification criteria. The scope of this work is enormous, but so is the importance. We appreciate efforts to capture the functionality across a broad range of needs.

ASHP convened a group of informatics pharmacist members from around the country to respond to the latest criteria on inpatient and interoperability criteria released on September 25th, 2006. This committee, which represents some of the best pharmacy informaticians in the country, contains members that have practical experience on dozens of information systems (both self developed and from leading IT vendors). An enormous amount of effort went into responding to the criteria and our emphasis is on medication management aspects in each section. Furthermore, our perspective lends itself to functionality that supports not only the pharmacist, but all health professionals in the medication use process to improve patient care.

The scope of this effort was dictated by CCHIT's time frame. Additional details can be provided as the proposal is finalized. As the CCHIT process moves forward, please feel free to call on our collective expertise to further refine the criteria dealing with medication management. We believe more and additional pharmacists' involvement will benefit the Commission's work. We would like to thank Rick Reeves for his help and insight into the CCHIT process.

The following points represent a high level view of the attached comments.

- Pharmacist verification functionality – This was the largest gap of functionality and it is our strong belief that this needs to be expanded upon in a separate section. JCAHO has reaffirmed the role of the pharmacist in reviewing medication orders for accuracy and completeness. Thus ensuring that during this process which is critical to patient safety and care there is functionality to give the pharmacist all needed information.

- Support of Standards – We support all of the standardization efforts to make interoperability a reality. A standard codified drug nomenclature will be needed to accomplish most of the interoperability goals. Support for RxNorm in this regard is critical.

- CPOE and Medication Management Certification – While we support the goal of facilitating seamless communication during the ordering, verification, dispensing and administering of medications; we also recognize that there are disparate systems that can work together to accomplish these goals. In this regard, our concern is that the current certification structure favors large integrated vendors at the peril of niche pharmacy systems. We encourage CCHIT to adopt a process to recognize systems and facilities where business issues would prevent joint certification.

Our detailed comments for each section of the inpatient and interoperability criteria are also provided to expand on the ground work done by CCHIT.

Members of the ASHP Ad Hoc Informatics Advisory Committee

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General Comments to CCHIT

Time to respond

The difficult task of developing these criteria for CCHIT is greatly appreciated by the provider community and should result in a safer system of patient care. Given the scope of the subject matter, ASHP convened a team of informatics pharmacists to respond in the best way possible. We found the comment period brief and our ability to respond with additional criteria was, to some extent, hampered by the concise time frame. The team involved was very committed to the effort and stands ready to review future drafts or proposed criteria.

Lack of Criteria on Pharmacist Verification

The lack of a specific requirement for pharmacist prospective review and verification of medication orders was a significant void. This review is critical for safe ordering of medications and is required by the Joint Commission of Accreditation of Healthcare Organizations (JCAHO) (Standard MM 4.10). Significant clinical systems exist to ensure this is done in a high quality manner. Below is a brief example of functional criteria we feel is essential to developing the 2007 standard.

- The system shall provide the ability to enable a pharmacist to review and approve every medication order.
- The system will display the physician order as it was entered.
- The system will allow the pharmacist the ability to view all alerts generated at the time of order entry.
- The system will allow the pharmacist to view all clinical decision support overrides and the reasons given.
- The system shall record user and date/time stamp for order verification related events, including order date/time, renewal date/time, and discontinuation date/time.
- The problem, diagnosis, reason or indication will be transmitted with the medication order.
- Any change the pharmacist makes to the dose, frequency, route, drug product, instructions or comment needs to go back to the CPOE system for physician co-signature. The system shall allow the institution to determine criteria for activation of modified orders without physician co-signature (i.e., which orders require physician co-signature prior to activation).

- The system shall accommodate therapeutic substitution without physician co-signature where institutionally specified. The system shall allow customization that recognizes the difference between therapeutic substitution and medication order changes that require physician co-signature.

Priority should be HIGH for Providers. Availability and compliance should be set for 2008.

Certification of CPOE/CDS and Medication Management as One

It is well understood that the process of medication management and CPOE is highly connected. The re-entering of orders from an ordering system to a pharmacy system is a not an acceptable practice in the hospital or ambulatory environment. We wish to bring to the attention of CCHIT that there are many examples of pharmacy system vendors working well with CPOE systems that have the integration required for certification.

An important issue in the method chosen by CCHIT to certify these products provides an unfair advantage to the large, multi-module vendors such as Cerner, Epic, Eclipsys, etc. The certification methodology requires the standalone, best-of-breed vendors, to negotiate with these larger competitors to gain certification. The issue is that the larger vendors have competing products. Therefore, there is no incentive for them to work with the smaller pharmacy vendors. It is common for larger vendors to not aggressively pursue an interface with stand alone pharmacy vendors. A common response is "If you want that functionality then use our product," even though quite often the needed functionality is not there with their product.

'Best-of-breed' vendors often are the primary source for cutting edge innovation due to their need to survive. For this reason, we ask that a provision for a 'best of breed' environment of pharmacy and CPOE systems certification be revisited. Certification should take into consideration the functionality of the software and its ability to communicate with other systems. It should not be predicated on whether other vendors are willing to "receive" the information. That should be left to the clients to negotiate.

Certification should also ***require*** vendors to communicate through standardized methodologies and nomenclature.

Value of Standardized drug nomenclature and Data Elements

CCHIT may wish to consider an approach where standardized data elements and their attributes must be clearly defined. Consideration for this standardization to be mandated for use by vendors has some important reasons. Here are four:

1) Mandated EHR data standards will allow development of interoperability to progress at maximum speed, both within and between vendor systems. We

understand that interface development and maintenance is expensive, and have witnessed first hand the problems associated with data elements existing on only one side of an interface. Even when a data element exists on both sides, there are problem if the attributes are different. This can have unintended consequences in system function and can also interfere with effective communication between nurses, pharmacists, and other clinicians.

Example: In a pharmacy information system and point-of-care (POC) system that are both from the same major HIT vendor:

- The pharmacy system supports PRN as a separate data element, but the POC system does not. Thus in the interface we concatenate the frequency (e.g. q4h) to PRN so the POC system sees q4hPRN.

- The POC bar coding system was designed with the assumption that all IV infusions come from the pharmacy. The work around for floor stock IV solution is to enter all floor stock IVs as PRN orders in the system. The vendor refuses to see the legal implication of this work around. As a result we have elected not to use their IV software for POC bar-coding. And of course we can not use any other vendor's software for IV POC bar-coding as the data elements are completely incompatible, and useless to our POC documentation system.

2) Mandated EHR data standards will help preserve a HIT free market. Failure to mandate EHR data elements maintains the status quo of the high costs of HIT interfaces for years to come. Eventually, one vendor may emerge as the de facto standard, and will have a monopoly. Mandating the EHR data standards now will preserve free market competition and all of its benefits. To be sure, the cost of this mandate will be high; but if the mandate is delayed the eventual cost will be much higher.

   Example: A large integrated health system recently changed EHR software vendors. The data structures of the old and new systems are different. They have about two decades of electronic medical records that are lost to the new EHR and will be required to print and store all of these rich electronic health records. If EHR data standard had been mandated 20 years ago all this data would still be available for daily clinical use and research. The longer we wait to mandate data standards the more data that will be lost to legacy databases.

3) Structure will allow for better analysis of data whether it is the administrative reports or the public health reports mentioned in Sections IF-6.2-1, IF-6.2.4, IF-6.2.6, IF-6.2.7, and IF-6.5.2-3. Whenever an informatics system is put into place for a wider variety of functions in the future, it will be is necessary to consider if the desired information will be available in a useable format in a timely fashion. It is very difficult and time consuming to retroactively delve into thousands of records and recode the information.

Some existing systems are not structurally well-designed for reports or statistical analysis. Therefore, now is the time to change the structure of the systems to ensure that the data will be available five years hence for retrospective studies.

Examples:
Certain data types greatly enhance the capability to perform statistics. Use of free text almost precludes the data from analysis. Restating the same data as choices allows for it to be recorded as drop down lists or radio buttons and analyzed as categorical data. Thus, the likelihood of having statistical significant differences is increased and misclassification due to misspelling is minimized. To this end, storage as continuous numeric variables is best if appropriate for the data.

Variables to be used in analysis need to be place in separate fields. For example, if information is requested on all PRN medication, the SIG, such as q4h prn, needs to be stored in two fields.

A data dictionary is essential. Standardized variable names and formats are necessary to access information which increases interoperability. Versioning of the data dictionary is important because changes in definition may affect the outcome of a report or query. This also gets to the heart of the Arden Syntax curly braces issue (need for a standard query format) that the HL7 CDS committee has been struggling with.

Data standards for medication orders and documentation of medication administration must be developed by an appropriate standards organization (NCPDP, or HL7) and compliance with the standard must be mandated by an appropriate organization (JCAHO, or HHS).

Every year we delay compounds this problem since healthcare data continues to be stored in legacy systems.

RxNorm must be part of this mandate as the industry greatly needs a standardized and nonproprietary drug products database. As such, we fully support the National Committee on Vital and Health Statistics: Second Set of Recommendations on E-Prescribing Standards that applies to both inpatient and ambulatory environments (below). We believe that CCHIT should require the RxNorm nomenclature for 2008.

4) HHS should take immediate steps to accelerate the promulgation and implementation of FDA's Drug Listing Rule in order to make the inclusion of RxNorm in the 2006 pilot tests as comprehensive as possible. Delayed promulgation may jeopardize the success of the 2006 pilot tests. This is also necessary to achieve the patient safety objectives of MMA.

Discrete data elements must be codified using a standard vocabulary so it is available for computerized clinical decision support (CCDS). The Institute of Medicine report identifies CCDS a high priority for patient safety and quality care.[1]

[1] Aspden P, Corrigan JW, Wolcott J, and Erickson SM (eds): PATIENT SAFETY Achieving a New Standard for Care. Quality Chasm Series. INSTITUTE OF MEDICINE, The National Academies Press. Washington, DC 2004.

COMMENTS:

Proposed Functionality for 2007Certification of Inpatient EHRs

IF-1.1.1 to 2.3.5

No comments.

IF-2.4.1 to 2.4.8 Manage Problem Lists

IF 2.4.1
Criteria: Create and maintain patient specific problem lists

Comment: Priority should be HIGH for Providers, Public Health, Patient, and Quality Organizations. JCAHO requires indication for some types of prescriptions, medical imaging, etc. SNOMED-CT should be the standard coding of problems, indications, pregnancy, lactation, etc. The standard will ensure the availability of this information for computerized clinical decision support (CDS). The IOM report entitled: Patient Safety – Achieving a New Standard for Care specifically identified CDS as a high priority for patient safety. Consider changing availability and compliance to 2008.

Please clarify the use of the word 'current'. For it may be used in reference to the HITSP conditions module where there are only four data elements; problem date; problem type; problem name; and problem code. The term currently implies both an active status as well as a recent date for an event (per SNOMED-CT Event codes e.g. October 1, 2006 –patient fell off ladder)

IF 2.4.2
Criteria: The system shall provide the ability to record the chronicity (chronic, acute/self-limiting, etc.) of a problem.

Comment: Priority should be HIGH for Providers, Public Health, Patient, and Quality Organizations. Consider changing availability and compliance to 2008. Broaden the term used since chronicity is only one type of qualifier that is relevant to the problem list. Others including severity should be valid, but constrained to SNOMED-CT Clinical Finding qualifiers and encoded as such.

IF 2.4.3
Criteria: The system shall record the user ID, name, and date of all updates to the problem list.

Comment: Priority should be HIGH for Providers, Public Health, Patient, and Quality Organizations. Consider changing availability and compliance to 2008. There should be an ability to record a series of verification dates for each problem; re-verification over time is common and may be accompanied by new comments/qualifiers for each problem.

IF 2.4.4
Criteria: The system shall provide the ability to deactivate a problem.

Comment: Priority should be HIGH for Providers, Public Health, Patient, and Quality Organizations. Consider changing availability and compliance to 2008. Please clarify the term deactivate as it is not a traditional term used to describe items on a problem list (would prefer this as a "status change").

IF 2.4.5
Criteria: The system shall provide the ability to re-activate a previously deactivated problem.

Comment: Priority should be HIGH for Providers, Public Health, Patient, and Quality Organizations. Consider changing availability and compliance to 2008. Again, the terms activate, deactivate, and reactivate are not used by clinicians and does not accurately describe how problem lists are maintained over time.

IF 2.4.6
Criteria: The system shall provide the ability to display inactive and/or resolved problems.

Comment: Priority should be HIGH for Providers, Public Health, Patient, and Quality Organizations. Consider changing availability and compliance to 2008. Include sorting and filter (hide from view) capabilities.

IF 2.4.7
Criteria: System shall provide the ability to manually order/sort the problem list.

Comment: Priority should be MEDIUM for Providers, Public Health, Patient, and Quality Organizations. Consider changing availability and compliance to 2008.

IF 2.4.8
Criteria: The system shall provide the ability to associate orders, medications, and notes with one or more problems.

Comment: Indication for medication use is a JCAHO requirement. Priority should be HIGH for Providers, Public Health, Patient, and Quality Organizations. Availability and compliance should set for 2008. Indication must be codified using a HL7 standard vocabulary to make it available to CDS. Documentation of Patient Teaching should be added to the list of things that shall be linked to a patient problem. Each problem may be associated over time with various medications, orders and notes etc. Past/ current

medications and text notes should remain linked and viewable; notes may include information regarding efficacy and toxicity experienced.

SNOMED-CT has been designated by the NCVHS to be the standard vocabulary for EHR. At a minimum the NCI subset of SNOMED-CT, which is used by the FDA Structure Product Labeling (SPL), should be implemented for these criteria.

IF-2.5.1 to 2.5.6 Workflow Management

GENERAL COMMENT

Successful implementation of an EHR system is directly dependent on the ability of staff to perform tasks associated with entering monitoring and reacting to the information that drives such a system. Given the need to manually enter much of this data, full implementation is rarely achieved. Thus workflow management is crucial to providing the required efficiency needed to counteract these additional barriers to productivity.

IF 2.5.1
Criteria: The system shall use system interfaces that support the management of human resources (i.e., personnel lists).

Comment: This support should include assignment queues and the ability to track, report, and analyze those queues through a dashboard or similar function. This will allow managers to improve responsiveness by quickly assessing and redistributing workload within a pharmacy. This increased efficiency should also allow for the allocation of additional pharmacy resources toward clinical activity. Where possible, the ability to interface with personnel resource management software should be encouraged.

This should include the assignment of queues and the ability to track and report on those queues in a dashboard format to allow for workload redistribution when required.

The system will be able to import existing enterprise personnel resource data files for personnel resource management, including adding/modifying/deleting in an automated manner. The personnel resource data file encompasses providers, nursing, pharmacy, and other clinical roles. EHRs should utilize existing data and not require additional redundant processes.

IF 2.5.2
Criteria: The system shall provide the ability to create and manage (task list) queues.

Comment: The creation of task lists should include verification queues through the assignment of patient care areas (nursing units). These queues should be assigned to pharmacists. In addition, time in queue and other measures should be trackable, reportable, and be available for analysis. These queues should be flexible enough to allow for stat and other "priority" type orders to automatically be moved to the top of the queue

as required. These queues should also provide the user with the ability to apply different "filters" which will allow the pharmacist to view various orders as needed.

For instance, this could be accomplished by establishing verification queues for groups of patient care units and assigning these queues to various pharmacists based upon staffing issues. This approach could vary from day to day. Subsequently, we should be able to monitor productivity information such as number of orders verified, time in queue by various attributes, patient location, and type of order, order status, and pharmacist. This will allow a manager to better distribute workloads across a changing staff.

The system will be able to support access to patient data and application functionality based on the role of a given resource. For example, a medical intern's application security rights will support medication order generation according to enterprise policy and be available to alerts that are dictated by role. For example, the ability to filter and sort medication orders supports the foundation of pharmacy operations.

IF 2.5.3
Criteria: The system shall provide the ability to distribute information to and from internal and external parties

Comment: Alerts should be definable as synchronous and/or asynchronous depending upon user definable parameters. These alerts should be distributed via external systems such as corporate email or paging systems. For this reason, data content should be standardized to facilitate consistent and reliable communication between these systems.

The system will be able to generate alerts to clinicians using multiple functionalities, both synchronous and asynchronous.

The system will be able to link internal application functionality to external application functionality. For example, the system can utilize the existing enterprise email system or paging system for alerting.

HL7 works to provide a structural means of communication, but the data content issues requires standardized - as NCVHS is currently supporting.

IF 2.5.4
Criteria: The system shall provide the ability to route notifications and tasks based on system triggers

Comment: These notifications should be highly customizable by practitioner, practitioner group, specialty, various patient parameters and any other "trigger" that will allow the systems to be built in a way that will eliminate false positives or negatives. The systems should use clinical decision support rules whenever possible.

The system will be able to use clinical decision support rules to generate notifications. These notifications are automatically prioritized according to the specific patient clinical situation and the data fields used within the alert.

IF 2.5.5

Criteria: The system shall dynamically escalate workflow according to business rules

Comment: This escalation should include both active and passive alerting mechanisms. For example, an unverified medication order for potassium already in queue could be elevated to a STAT medication if the laboratory reports the patient as hypokalemic. If the STAT order remains in queue for longer than a predefined time, a supervisor is actively alerted through a pager system or other means.

New orders should automatically change to STAT if a lab value comes back that would indicate this is necessary per pre-defined protocol.

The system can automatically and manually escalate the alert to the clinical chain of command according to specified time points after the initial alert has been generated. Workflow processes are supported fully when triggers generate alerts and continue to track the alerts until action is taken by an appropriate clinician.

IF 2.5.6
Criteria: The system shall dynamically redirect workflow according to business rules

Comment: The systems will track alert and work queues. When items reach a predefined milestone without resolution, the 'task' is automatically reassigned to the next person inline and so forth until the issue is resolved.

The system will track the responses to the alert with audit trails, including the clinician, the response captured, and the date/time stamp.

The system will track all alerts as open and continue escalation policies until a clinician acts upon it.

IF-2.6.1 to 2.7.8

No comments.

IF-2.8.1 to 2.8.3 Manage Results

IF 2.8.1
Criteria: The system shall provide the ability to present numerical and non-numerical current and historical test results to the appropriate provider.

Comment: To comply with ISMP recommendations, leading zeros and commas should be part of the representations (0.04mg versus .04 mg and 1,000,000u versus 1000000u).

IF-2.9.1 to 2.9.12 Manage Allergy, Intolerance and Adverse Reaction List

IF 2.9.1
Criteria: The system shall capture and store lists of medications and other agents to which the patient has had an allergic or other adverse reaction.

Comment: All allergens, drugs (including multi-ingredients drugs), excipients (inactive ingredients), foods, and environmental factors must utilize standardized names, definitions and codes. All vendors must use the same standard to enable interoperability (FDA UNII codes for drug ingredient allergens and RxNORM for brand name drugs). See NCVHS recommendation letter to HHS, September 2006. Therefore, we would recommend that the criteria include standard codification of allergens.

Route of administration: ADR/ Drug Intolerance should optionally allow entry for a route of administration. Routes of administration are important especially for assessing drug intolerance/adverse reactions.

Allergen groups: As stated in the NCVHS September letter to HHS recommending that the NDF-RT classes be used for documenting allergen groups- this is an untested domain data set and was not designed for this purpose.

IF 2.9.2
Criteria: The system shall capture non-drug agents to which the patient has had an allergic or other adverse reaction.

Comment: retain the ability to document items that do not appear on a coded list.

IF 2.9.3
Criteria: The system shall provide the ability to capture the reason for entry of the allergy, intolerance or adverse reaction

Comment: It is unclear what is meant by “reason” versus “type.” This should specify that the reaction of the allergy, intolerance or adverse reaction should be captured in a codified manner. For example allergy: codeine reason: GI upset has a completely different meaning that allergy: Codeine Reason: Shortness of breath.

IF 2.9.4

Criteria: The system shall provide the ability to specify the type of allergic or adverse reaction.

Comment: Each substance listed as producing an allergic or adverse reaction should have an attribute indicating that the reaction was a 1) suspected hypersensitivity-medicated reaction, 2) side effect/intolerance, 3) idiosyncratic reaction, or 4) unknown. This indicator is necessary as differing algorithms will be utilized on future checks of drug orders against this information

IF 2.9.5
Criteria: The system shall provide the ability to capture the severity of a reaction.

Comment: Most clinical information systems already provide specification of severity of patient's reactions or allergic manifestations. Consider changing availability to 2007.

IF 2.9.6
Criteria: The system shall provide the ability to explicitly indicate that a patient has no known drug allergies.

Comment: A series of dates associated with this patient data is needed and a historical note should be added when it has been re-verified.

IF 2.9.7
Criteria: System shall provide for the ability to explicitly indicate that the allergies are Unknown and require a reason (e.g., patient unconscious) and have alerts at given intervals to request provider update from Unknown.

Comment: The system will provide an allergy category: “Unable to assess allergies”.

IF 2.9.8
Criteria: The system shall provide the ability to capture the source of allergy, intolerance, and adverse reaction information.

Comment: There is a need for the capability to capture allergy/intolerance history information that does not need to be a coded list, but does need to be viewable in alert messages triggered by the information in the future, i.e. information as given by patient’s family member and medical chart.

IF 2.9.9
Criteria: The system shall provide the ability to remove an item from the allergy and adverse reaction list.

Comment: "Removal" is NOT really acceptable in a medical chart (cannot remove a medical problem wither). There needs to be the capability to have a STATUS for each allergen or intolerance ingredient. It should be clear that when a status is changed to inactive that algorithm check will not utilize this part of the patient history. Any status change will need appropriate sign-off and rationale. A notation here that the patient was RE-CHALLENGED without negative consequences would be a reason for a status change.

IF 2.9.10
Criteria: The system shall provide the ability to specify the reason for removing an allergy/allergen from the allergy list.

Comment: See above- removing an item is NOT an appropriate option via medical charts, but status change capability should be provided.

IF 2.9.11
Criteria: The system shall record the removal of items from the allergy list, including the ID and name of the user who removed the item and attributes of the items removed.

Comment: none.

IF 2.9.12
Criteria: The system shall provide the ability to display information which has been removed from the list or prior information that has been modified.

Comment: none.

NEW CRITERIA RECOMMENDATION FOR ALLERGY SECTION

Allergen and intolerance checking algorithms should be performed any time an allergen update is made or any time the drug orders/medication lists are updated. System will provide "reverse" allergy screening where the addition of an allergy screens active orders and alerts the appropriate clinician.

System must include level of reliability or certainty of history information as part of alert message, since it is important for those clinicians considering overriding such an alert.

The system will provide a method to force review of allergy information (at specified times, venue, or condition).

Allow customization for allergy vs ADR/Intolerance drug checking algorithms. For example route may be important for ADR/Intolerance, while cross-sensitivity is

important for allergy. Other patient parameters may be used (e.g. phenotype, ethnicity) to make alerts more patient specific.

Provide the ability to indicate if an added allergy should be added to a patient's problem list.

The System will support the documentation of combination medication as allergies.

The System will support a client determined threshold to provide an alert to prompt users to update allergy information. For Example: If the system detects that a review of known allergies has not occurred within a user specified time period (i.e. 2 yrs.) the system prompts the user to provide an update.

IF-2.10.1 to 2.10.3 Manage Patient Clinical Measurements

IF 2.10.1
Criteria: The system shall capture patient vital signs as discrete elements of structured or unstructured data, such as blood pressure, temperature, heart rate, respiratory rate, height, weight, psychiatric symptoms, and daily functioning.

Comment: Discrete data elements must be codified using HL7 standard vocabulary so it is available for CDS. In particular, height and weight should be required structured elements (with convertible units of measure) so that the information can be readily utilized for drug dosing algorithm, renal function assessment algorithms, etc. (NOTE: The Institute Of Medicine has listed CCDS as a high priority for patient safety and quality care).

IF 2.10.2
Criteria: The system shall capture other clinical measures as discrete elements such as peak expiratory flow rate, size of lesions, oxygen saturation, body mass index and severity of pain.

Comment: All discrete data elements must be codified using HL7 standard (or similar) vocabulary.

IF 2.10.3
Criteria: System shall capture data directly from biomedical devices.

Comment: All discrete data elements must be codified using HL7 standard (or similar) vocabulary. Also, programmable biomedical devices (e.g. smart medication pumps) should be able to receive instructions (e.g. infusion rate, drug concentration, etc.) from the clinical information system to avoid programming errors at the bedside. Various

medical devices including those that deliver pharmaceuticals (e.g., smart pumps) should have the capability to download data into CIS.

IF 2.12.1 to 2.14.1

No comments.

IF 3.1.1 to 3.1.16 Manage Orders Sets

IF 3.1.1
Criteria: The system shall provide the ability to present order set(s)

Comment: The system will be able to selectively provide access to order set(s) based on user role, service, department, and other limits.

Order Set Priority should be HIGH for Providers, Patient, and Quality Organization. Order Sets are critical to the success of CPOE implementation. Consider making availability and compliance 2007.

IF 3.1.2
Criteria: The system shall provide the ability for individual items in an order set to be selected or deselected.

Comment: The system will provide a way to require certain orders within the order set to be required. The system will provide a way for the requirement of a single selection within subsets of the order set. (e.g., single diet order)

IF 3.1.3
Criteria: The system shall provide the ability to record each component of an order set that is ordered.

Comment: The system will maintain parallel functionality between a stand alone instance of the medication order and the functionality within an order set, including the display and data field content.

The system will support the defaulting of data fields within each order of the order set, including both a “locked” and “override” attribute for each data field.

The system will store information in individual searchable fields using variables formatted for later analysis (numerical, drop down boxes, and standardized)

The system will have a Data Dictionary to maintain present/past definitions and relevant active periods.

IF 3.1.4
Criteria: The system shall provide the ability to define a set of related orders to be subsequently ordered as a group on multiple occasions.

Comment: The system will be able to provide an attribute across the order set to identify "linked" orders and the "name" of the original order set.

The system can identify this attribute within the HL7 message.

IF 3.1.5
Criteria: The system shall provide the ability to modify order sets.

Comment: The system will be able to support order set modification by role. All order sets can be provided at user role, service, etc.

IF 3.1.6
Criteria: The system shall provide the ability to include in an order set orders for medications, laboratory tests, imaging studies, procedures and referrals.

Comment: The system will provide order set orders that can include all medication order types. The system will provide appropriate informational messages with order sets, including reminders.

IF 3.1.7
Criteria: The system shall provide the ability to display orders placed through an order set either individually or as a group.

Comment: The system will provide filters for display of order sets within different modules. (e.g., eMAR module displays, Order displays, and Clinical displays designed for disease specific or protocol specific requirements).

IF 3.1.8
Criteria: The system shall provide the ability for a provider to choose from among the order sets pertinent to a certain disease or other criteria.

Comment: The system will provide the ability to display subsets of order sets within browsers. (e.g., filters, categories)

IF 3.1.9

Criteria: The system shall allow the configuration of defaults within individual orders details within order sets.

Comment: The system will provide individual orders with default values. These defaults may be locked down or accessible for modification depending on the enterprise policy.

There is a need for the ability to independently lock down fields such as route or dose unit of measure. This would reduce medication errors.

IF 3.1.10
Criteria: The system shall allow a provider to repeat an entire order set on the same patient.

Comment: The system will provide the ability to "re-order" the entire order set.

IF 3.1.11
Criteria: The system shall allow a provider to create a set of favorite order sets to facilitate retrieval and ordering.

Comment: The system will provide users with the ability to create and share order sets.

IF 3.1.12
Criteria: The system shall allow the provider to incorporate choices in an order set for a medication or other intervention.

Comment: UNCLEAR what "incorporate choices" means.

IF 3.1.13
Criteria: The system shall allow a provider to check that no more than one of multiple options presented for an order is selected.

Comment: The system will provide the means for establishing a requirement for a single selection within subsets of the order set. (e.g., single diet order)

IF 3.1.14
Criteria: The system shall provide the ability to incorporate text instructions or recommendations within order sets.

Comment: The system will provide appropriate functionality to develop informational messages within order sets.

The system will provide functionality to link future reminders with the original orders. For example, follow up to a TB test in three days will be classified as a future actionable event.

IF 3.1.15
Criteria: The system shall provide the same order checking as with individual orders.

Comment: The individual order in an order set will function the same within the database as the standalone order.

The individual orders will be managed in the same manner and will therefore utilize CDS alerts, dose checking validation, dose standardization, allergy and other available checking options.

The system will provide functionality for ad hoc checking by a clinician outside of the entry of a new medication order.

IF 3.1.16
Criteria: The system shall provide vendor facilitated access to starter set of order sets.

Comment: The system shall provide detailed documentation on starter sets. Due to the nuances of each enterprise build, examples of starter set orders may be available as part of a separate region.

Standard protocols, for example those pediatric chemotherapy protocols defined internationally, will be available as part of starter order sets.

RECOMMENDATIONS TO ADD AFTER SECTION 3.1.16:

IF 3.1.17 System can limit conditions under which order sets can be viewed.
Limit access to drug by patient attributes, location attributes, inpatient or outpatient status, age, gender, clinical service, pregnancy and lactation status, disease state, and other system defined parameters. Medications shall be blocked when not allowed for certain pts. (E.G., do not give to infants under 2 year old) or when meds not allowed on non-ICU floors. Support for standarized infusion concentrations can be supported. User role can limit the order sets which can be viewed.

IF-3.2.1 to 3.2.8 Support for Order Sets

IF 3.2.1
Criteria: The system shall provide the ability to create order sets.

Comment: System needs to handle multiple standardize forms for different types of drugs. Examples include oral med, IV med diluted (dosed either by rate or ran over X hours), IV Med push (know to send only vial, need total dose) TPNs, additives, and heparin insulin sliding scale
Ordering checks can be specific to form type. Specialized order sets for OB/GYN, operating room and emergency department specialties often need specialized order sets to accommodate their specialty.

IF-3.3.1 to 3.5.18

No comments.

IF-3.6.1 to 3.6.3 Manage Blood Products and Other Biologics

IF 3.6.1
Criteria: The system shall interface with systems of blood banks or other sources to manage orders for blood products or other biologics

Comment: System shall provide bar coded administration of all blood products. This was mandated by the Federal Food and Drug (FDA) in 2004 for implementation in 2006. See US FDA Register: February 26, 2004 (Volume 69, Number 38) Rules and Regulations. P 9119-9171; and US FDA Guidance for Industry Bar Code Label Requirements, Questions and Answers www.fda.gov/cber/gdlns/barcode.htm

Priority is HIGH for Providers, Patient, and Quality Organizations. Availability and Compliance is 2007.

IF 3.6.2
Criteria: The system shall provide the ability to capture use of such products in the provision of care.

Comment: Bar code administration shall record in eMAR or other appropriate form in the EHR. The system shall record, at a minimum, all legally required information (Federal and State).

Priority is HIGH for providers, Patient, and Quality Organizations. Availability and compliance is 2007.

IF 3.7.1 to 3.7.44 Manage Medication Orders

IF 3.7.1
Criteria: The system shall create medication orders with sufficient information for correct filling by pharmacy.

Comment: It should be noted that the correct information for medication order fulfillment is often different information than the order. For example, IV infusions ordered in a mg/kg dose will need additional information associated with the order once it is received in the pharmacy for the concentration and the amount/ volume the order needs for filling. This information is NOT needed to be done by the ordering physician but does need to be created by the pharmacy personnel prior to filling. This is typically done in the pharmacist verification step. Pharmacist verification is not addressed sufficiently and is addressed in our comments in another section.

Criteria should recognize the requirement of pharmacy verification. Therefore the medication orders should have sufficient information for correct filling and pharmacist verification. This will include override reasons for non-formulary meds, allergy warnings, interaction warnings and other clinical messages.

IF-3.7.2
Criteria: The system shall provide the ability to set required fields for a complete medication order, including Medication Name, Dose, Route and Frequency.

Comment: These data elements must be standardized by HL7 or NCPDP as stated above. It is important to realize that there are many data elements that make up a drug order. The following is not a complete list but it illustrates the point:

For typical Rx: Indication, DoseAmount, DoseUnit, Dosage Form, Dose Limit, Priority, Duration, Comments, Start date/time, Stop date/time, and Fill Quantity.

For IV infusions add: volume, additives, infusion rate, dose rate, infuse over, alternate with.

For PCA add: Basal rate, Demand interval, and Demand dose.

It is very important for physicians to realize that although these and other data element need to exist uniformly in CPOE, PIS, and POC systems they do not need to be exposed to the user. Indeed, many can be pre-populated. CPOE systems must be physician friendly and data entry fields must be exposed in context to the order type. Additionally, well designed CPOE systems only require 3-5 key strokes for simple medication orders, and order sets simplify this further.

IF-3.7.3
Criteria: The system shall record user and date/time stamp for medication order related events, including order date/time, renewal date/time, and discontinuation, date/time

Comment: Please see statement on pharmacist verification. These elements apply to verification as well.

IF-3.7.4
Criteria: The system shall allow for co-signature of orders and allow assignment of cosign provider at the time of order entry, capturing the identity of the prescribing provider and cosigner provider for all medication orders. Orders requiring co-signature shall retain both prescriber's identities in the electronic copy of the order.

Comment: none.

IF-3.7.5
Criteria: The system shall provide the ability to cosign medication orders via an electronic process.

Comment: none.

IF-3.7.6
Criteria: The system shall update the medication history/profile with the newly prescribed medications.

Comment: There should be an order status of “pending pharmacist verification.” Please consider this as future criteria.

IF-3.7.7
Criteria: The system shall provide a list of medications to search from, including both generic and brand name.

Comment: This is already available in some CPOE systems and theses structures have the ability to add synonyms such as therapeutic class and a list of indications to ease the search process. Consider changing availability to 2007.

IF-3.7.8
Criteria: The system shall maintain a coded list of medications. With a unique identifier for each medication

Comment: Consider RxNorm as a common coding standard, the recommended coding structure put forth by the NCVHS to CMS.

IF-3.7.9
Criteria: The system shall display common content for medication order details including strength, route, frequency and comments by the ordering clinician.

Comment: Please consider that display for different users may vary. Display for a pharmacist may be different than what is needed to display for a nurse.

IF-3.7.10
Criteria: The system shall check for daily dose outside of recommended range for patient age (e.g., off-label dosing).

Comment: none.

IF-3.7.11
Criteria: The system shall provide the ability to create provider specific medication lists or provider "favorites" of the most commonly prescribed drugs or order sets including the default dose, route and frequency.

Comment: none.

IF-3.7.12
Criteria: The system shall provide the ability to select a drug by therapeutic class.

Comment: Some CPOE systems already allow the addition of synonyms to the drug database for search purposes. There is no reason that therapeutic classes and a list of indications could not be added. Consider changing the availability to 2007 for non-coded therapeutic class. NCPDP or HL7 should tackle a unified therapeutic class standard. This should be a priority for 2008.

IF-3.7.13
Criteria: The system shall allow filtering for order details including strength, route, frequency and comments by the ordering clinician.

Comment: none.

IF-3.7.14
The system shall display and store information received through health plan/payer formulary checking when e-prescribing at discharge.

Comment: This will occur only if there is an adoption of a common codification scheme for medications. RxNorm is what is currently recommended.

IF-3.7.15

Criteria: The system shall provide the ability to designate an expiring order and allow the prescriber to reorder a prior medication order without re-entering previous data

Comment: none.

IF-3.7.16
Criteria: The system shall allow filtering for order details including strength, route, frequency and comments by the ordering clinician.

Comment: none.

IF-3.7.17
Criteria: The system shall provide the ability to create provider specific medication lists or provider "favorites" of the most commonly prescribed drugs or order sets including the default dose, route and frequency.

Comment: none.

IF-3.7.18
Criteria: The system shall provide the ability to create prescriptions electronically at the time of Discharge.

Comment: This criteria requires further clarification of what is meant by "electronically". Clarification is needed in regards to distinguishing between the entry and storage of electronic prescriptions vs the electronic, printed or fax transmission of the prescription.

IF-3.7.19
Criteria: The system shall allow dose calculation for patient-specific dosing for mg/kg and BSA where appropriate in the medication order entry process.

Comment: Consider changing availability to 2007. Rules engines and clinical content from knowledge base providers are already available.

IF-3.7.20
Criteria: The system shall have the ability to perform estimated Creatinine Clearance calculations and display this information to the prescriber at the time of order entry.

Comment: Consider changing availability to 2007. Rules engines allow automatic collection of patient information for calculation of creatinine clearance or GFR by any method. This includes different methods for different patient populations and/or different providers.

IF-3.7.21
The system shall check and report allergies, drug-drug interactions, duplicate therapies, and other potential adverse reactions, when new medications are ordered.

Comment: While we agree that this is imperative, the issue of better quality alerting with less false positive alerts should be considered. It has been shown that up to 90% of the alert generated from current drug-interaction and allergy systems are false positive. This must be address for CDS to become viable.

In addition to displaying such warnings, the system should document what warnings have been displayed and the user response to the alerts.

IF-3.7.22
Criteria: The system shall display patient specific dosing recommendations based on weight, age, and renal function.

Comment: Consider changing availability to 2007. Rules engines allow automatic collection of patient information, lab results, etc., for patient specific dosage calculations. Theses include pharmacokinetic and pharmacodynamic dosing methods.

IF-3.7.23
Criteria: The system shall display patient specific dosing recommendations based on illness or diagnosis.

Comment: Same comment as IF-3.7.19 and IF-3.7.22 – although in order for the rules engines to retrieve and use this info for dosing, diagnosis and problem will need to be standardized using a HL7 vocabulary like SNOMED-CT.

IF-3.7.24
Criteria: The system shall provide the ability to prescribe uncoded or non formulary medications.

Comment: none.

IF-3.7.25
Criteria: The system shall alert the user at the time a new medication is prescribed that drug interaction, allergy, and duplicate therapy checking will not be performed against the uncoded medication.

Comment: See comment for IF3.7.21.

IF-3.7.26
Criteria: The system shall provide the ability to update clinical decision support databases.

Comment: none.

IF-3.7.27
Criteria: The system shall alert the user if the clinical decision support information is outdated based on the frequency of updates.

Comment: none.

IF-3.7.29
Criteria: The system shall provide for entering of pre-admission orders and keep them inactive with the ability to set a timeframe for which this applies and /or active admission shall activate the medication orders

Comment: none.

IF-3.7.30
Criteria: The system shall provide the ability to associate a diagnosis or reason with a medication order at the time of prescribing.

Comment: This should be a high priority for inpatient as well. JCAHO is already requiring indication for pain prescriptions. Currently indications are free text in most CPOE systems. These need to be codified in a standard vocabulary.

SNOMED-CT encoded problem list should have links to medication orders. Functionality available for pharmacist workflow (and others) to first select drug and review its indications; (indications that are then linked to SNOMED-CT codes)- select and store a SNOMED-CT code.

IF-3.7.31
Criteria: The system shall provide the ability to display the problem, diagnosis or reason in the electronic copy of the medication order

Comment: none.

IF-3.7.32

Criteria: The system shall provide links to general prescribing information at the point of prescribing.

Comment: Drug orders (pending or completed) should have links to full text drug information. General prescribing information will be provided by a referenced and edited source that is maintained with updates minimally every 6 months. The system should have a context sensitive information-button similar to technology that automatically drills down in to a monograph based on the current data field the provider is working on.

IF-3.7.33
Criteria: The system shall provide the ability to add reminders for necessary monitoring or follow up tests based on the medication prescribed.

Comment: Such reminders should be applied to nursing and/or pharmacy worklists.

IF-3.7.34
Criteria: The system shall allow entry of "Pt Taking Own Meds" and include in Med List

Comment: none.

IF-3.7.35
Criteria: The system shall allow for a subsection of orders to be written to be active for an interim duration, pre, intra & post procedures.

Comment: In addition, the system should support the entry of orders that start upon a specific trigger event such as end of procedure or completion of another order.

IF-3.7.36
Criteria: The system shall facilitate Medication Reconciliation at site specified times e.g.. Admit, transfer, discharge.

Comment: This is already a JCAHO requirement. Consider changing availability to 2008 or possibly 2007.

This is a very vague and general statement. Suggest more granular criteria such as:

- The system will have the ability to enter prior drug therapy.

- The system shall have the ability to retrieve drug history information from 3rd party sources and pharmacies (post 2008 criteria).

- The system shall present the admission drug history and latest drug profile prior to writing discharge medications.

The system will allow the documentation when reconciliation has occurred with the patient and what medications were included in the reconciliation. The system shall provide alerts or reminders of unreconciled therapeutic coverage.

IF-3.7.37
Criteria: The system shall allow the provider to change Medication orders including dosing information without provider having to manually discontinue previous order.

Comment: In addition, the system needs to keep a history of the changes so that the before and after values of the order elements can be determined.

IF-3.7.38
Criteria: The system shall reflect changes that occur during Medication Reconciliation on the Medication Profiles.

Comment: none.

IF-3.7.39
Criteria: The system offers a print report of Medication Reconciliation Process Medication List

Comment: none.

IF-3.7.40
Criteria: The system provides the prerequisite of allergy information required prior to Medication Order Entry occurring.

Comment: Availability should be moved to 2007. Documenting allergy information and allergy checking with CPOE is an accepted standard of care. Interoperability with other systems would be nice, but the patient's allergies must be in the CPOE system for checking before medication order entry begins.

IF-3.7.41
Criteria: The system seamlessly transmits Medication orders from the CPOE system to the pharmacy application so that patient care & pharmacy processes are based on the same information and orders need not be reentered.

Comment: Availability should be moved to 2008 and ideally to 2007. Closed loop functionality between CPOE and the inpatient pharmacy information system is essential for patient safety. See comments with IF3.7.1 and IF3.7.2.

Need clarification of "seamlessly". With lack of standards for many of the components of prescription data, such transmission will not be seamless. Most pharmacy systems will require manual selection of patient, medication and coded sig. Seamless would be better described as transmission in such a way as to not require translation of the original order elements in the pharmacy application. Any translation, manual or automated, has the potential to introduce medication errors. If automated translation occurs, then a pharmacist must verify the translation against the original order.

Thus standardized methodologies and Rx data elements must be uniform across all systems (CPOE, Pharmacy information system, POC).

IF-3.7.42
Criteria: The system shall provide the ability to designate from orders for a prior level of care those to be continued as new orders for a new level of care without necessitating reentry of those orders.

Comment: none

IF-3.7.43
Criteria: The system shall provide the ability to spell out UNITS, use Thousands and Millions as part of expressing large doses and allow the use of commas in doses expressed in thousands in dosage fields.

Comment: These issues of prescription clarity are extremely important patient safety concerns. These prescriptions data elements need to be standardized by either NCPDP or HL7. Consider moving to 2008.

IF-3.7.44
Criteria: The system shall provide the ability to search from medication lists which provide for Tall Man Lettering for clarity.

Comment: Tall Man Lettering is an important feature for patient safety. Consider moving availability and compliance to 2007.

NEW CRITERIA Suggestion:

The CPOE system should support the concept of restricted drugs or procedures to specified providers. For example certain antimicrobials are restricted to ID specialists; most chemotherapeutic agents are restricted to oncology specialists. The CPOE system shall allow support for this notion in a non-hierarchal way. That is to say that the system

shall not use a numerical system that allows any provider with an authorization number high enough to order meds that are restricted to a different group. Example: ID providers have an authorization number of 12 and oncology providers have an authorization number of 13. In this scenario oncologists could order antibiotics restricted to ID providers.

NEW CRITERIA Suggestion:

User Restrictions by Class: Example: Medical students can enter orders in CPOE, but these orders are not transmitted to pharmacy or nursing until verified by a resident or attending.

NEW CRITERIA Suggestion:
Patient name, gender and age/dob will display prominently on all order screens.

IF-4.1.1 to 4.1.11 Manage Medication Lists

IF-4.1.1
Criteria: The system shall provide the ability to capture patient-specific medication lists

Comment: Medication drug list should contain active and inactive medication orders. Active medications should be the default display, with an option to view active and inactive together.

Medication drug list shall be customizable, ideally to the patient care unit or even individual users.

The available data elements to construct medication lists shall be discrete data elements as described in the comments for IF 3.7.1, and IF 3.7.2.

Medication list functionality shall include filtering functionality for date ranges, order status, and other enterprise data fields.

For example, a Pharmacy operation needs the flexibility to manage the verification que to support workload - STAT orders need to be addressed differently than standing orders.

IF-4.1.2
Criteria: The system shall display and report patient-specific medication lists

Comment: Patient allergies, age, weight, abnormal hepatic or renal function, CrCl, diagnoses and location appear on all med lists headings.

The display and reports shall support enterprise defined attributes to be available on the headers. Furthermore, the date / time range of the report needs to be clearly stated in the report header. Additionally, it is preferable that clarity is provided regarding data definition and formulation. .

To support medication reconciliation processes, the medication lists shall contain both the inpatient and outpatient phase of the patient continuum.

The display on screen and report MUST clearly state that the data is continued on additional screens or hardcopy (Page one of two; END OF REPORT) so the clinician is fully aware of the data available.

IF-4.1.3
Criteria: The system shall provide the ability to capture the details of the medication such as ordering date, dose, route, and sig (description of the prescription like the quantity) when known.

Comment: System should make more order detail readily available by single click (or double click on drug) including who ordered which medication and when.

IF-4.1.4
Criteria: The system shall maintain other dates associated with medications such as start, modify renewal and end dates.

Comment: Include suspend/resume dates and times.

The full history of the order must be available to add to the display or report.

IF-4.1.5
Criteria: The system shall provide the ability to enter non-prescription medications, including over the counter and complementary medications such as vitamins, herbs and supplements.

Comment: As mentioned this is an important medication reconciliation requirement of JCAHO. Consider availability and compliance for 2008. Priority should be HIGH for Providers, Patient, and Quality Organizations. Any of these products that are to be continued in the hospital drug-interactions software should provide screening if possible. If these products are to be continued after discharge, results of drug-interactions screening against discharge medications should be available for discharge counseling.

The entry of non-prescription medication must maintain the same data fields as the medication orders for appropriate database storage and maintenance. The entry must maintain an audit trail and follow the same rules of update as the medication orders.

IF-4.1.6
Criteria: The system shall provide the ability to display current medications only

Comment: The system should maintain filters for display and reports according to the status of the order.

IF 4.1.7
Criteria: The system shall display medication history for the patient.

Comment: This should be an important patient safety goal for interoperability.

The incorporation of multiple records for the same medication order must be manageable by the database (e.g., an inpatient order becomes discharge prescription, becomes record from Pharmacy Benefits Management company, becomes inpatient history record). By the appropriate design and unique identification of the order - the redundancy can be managed.

IF-4.1.9
Criteria: The system shall provide the ability to print a current medication list.

Comment: Printing of patient's current medication list should be a high priority for Provider, Patient, and Quality organizations. This is important for scheduled and unscheduled down times of the system. It may also be important for patient/family teaching.

Medications can be organized by several user-chosen methods such as date & time, provider, scheduled medications being separated from PRNs, and active orders separate from cancelled and stopped. This applies to active orders only.

The system will be able to generate an adhoc clinical review using the CDS rules so the current user can be made aware of alerts.

IF-4.1.10
Criteria: The system shall include standard medication codes associated with items in the medication list.

Comment: There are issues with current medication coding systems like NDC numbers and propriety drug databases like NDDF. Hopefully, RxNorm will be available soon to correct these problems. This should be marked as a High priority for Providers and Patient. Resolving the medication coding issues should be a high patient safety issue. Consider changing availability compliance to 2008.

IF 4.1.11
Criteria: The system shall provide the ability to enter or further specify in a discrete field that the patient takes no medications

Comment: none

NEW CRITERIA Suggestion:

The system shall allow entering of drug-independent comments that affect medication administration and if appropriate when they end such as Central Line Access Available, NPO for surgery on “date”, pt has PEG, pt has NG tube.

NEW CRITERIA Suggestion:

The eMAR shall allow attaching a comment to an individual schedule dose, such as "draw Peak and Trough around 4th dose.". This comment must not appear on any other scheduled dose.

IF 4.2.1 to 4.2.25 Manage Medication Administration

IF-4.2.1
Criteria: The system shall present the list of medications to be administered over a selectable date time range.

Comment:
For optimal functionality prescription data elements (and their attributes) must be consistent between the pharmacy system, CPOE, and point-of-care system (nursing), to avoid miscommunication and medication errors.

IF-4.2.3
Criteria: The system shall display instructions for administration of all medications on the list.

Comment: This could be optional in CPOE, but is absolutely required for nursing and pharmacy.

IF-4.2.4
Criteria: The system shall notify the clinician when specific doses are due if the clinician is online during scheduled administration times.

Comment: Change availability to 2007. This functionality is already available in systems with eMARs.

IF-4.2.5
Criteria: The system shall provide the ability to document medication administration.

Comment: Ability for number of boxes on MAR to be different than number of times pharmacy sends new bottle, (for continuous IVs)

IF-4.2.6
Criteria: The system shall check and report allergies, drug-drug interactions, and other potential adverse reactions, when new medications are about to be given.

Comment: Drug interaction and allergy checking of new medications at the point-of-care (nursing level) is an essential patient safety function for STAT orders that must be given before pharmacy has a chance to verify orders. Few point-of-care systems have this ability and this should be a High Priority for Providers and patient safety.

Suggest cumulative dose checking (in the last 24 hours) for specified ingredients- especially for prn orders to ensure max doses are not exceeded (e.g. prn acetaminophen orders along with prn Viodin etc.)

IF-4.2.7
Criteria: The system shall check and report other potential adverse reactions, when new medications are about to be given

Comment: Change availability and compliance to 2007 as this technology is already available commercially from McKesson, Siemens and other vendors. Rules engine can help prevent these problems. For example checking the cumulative dose of acetaminophen over the previous 24 hours to ensure the dose the RN is about to give will not exceed 4 grams for adult non-liver patients or 2 grams for adult liver patients. This should be a HIGH priority for providers. Obviously, an eMAR is required for this to work.

IF-4.2.8
Criteria: The system shall provide the ability to capture and utilize other clinical data pertinent to the medication administration

Comment: Have all documentation in one place so nurses do not have to go to multiple systems to document meds. Include ability to chart Input and output

IF-4.2.9

Criteria: The system shall provide ability to document medication administration using a positive ID technology for medications, patients and employees - such as bar codes or RFID

Comment: Change availability to 2007. This technology is already available from most major vendors and is currently in use in about 12 to 20% of US hospitals. Change priority to HIGH for Patient.

IF-4.2.12
Criteria: The system shall display overdue medications in a more obvious format (ex. red/bold) compared to in a manner which distinguishes them from other medications

Comment: Have different types of medications represent by different colors continuous, IV, PO, and PRN

Ability to update time for next prn when dose is taken

Ability to see different time periods on one screen (shift, day)

Ability to document a reason for meds not given or given late (Pt in surgery)

IF-4.2.15
Criteria: The system shall provide ability for second provider to witness - co-document administration.

Comment: Consider changing availability and compliance to 2007. Change priority to HIGH for providers and patient. This is a patient safety issue.

Such functionality should be optional by medication in order to support specific lists of high alert medications.

IF-4.2.17
Criteria: The system should provide alert/icon indicating pharmacy has reviewed or other decision support (alerts were overridden).

Comment: This item is extremely important for pharmacy verification. In addition the system should support the entry of override reasons when medications are administered prior to pharmacy verification.

IF-4.2.19
Criteria: The system shall be able to report medications not given or given late (site defined) and export result for administrative review.

Comment: Ability to total medication amounts in combination medications for pain meds (acetaminophen).

Ability to calculate total daily dose of pain meds, including PRNs. This is already available. Consider changing availability to 2007.

IF-4.2.21
Criteria: The system shall operate in conjunction with automated dispensing machines.

Comment: This is already available. Change availability to 2007.

Needs functionality to specify where the medication is to be sourced from for administration and also provide order information to the ADM's to support accurate product selection and controls to support legal and safety needs in ADM dispensing. When items are removed from the ADM for a patient that do not match an existing order then an order will be created to specify that override dispense.

IF-4.3.1 to 4.3.15 Support for Drug Interaction Checking

IF-4.3.1
Criteria: The system shall check for potential interactions between medications to be prescribed and current medications and alert the user at the time of medication ordering if potential interactions exist.

Comment: At a minimum drug interaction checking should be implemented with drug ingredients (active ingredients and inactive ingredients), as well as the route of administration specified, so that false positive alerts are minimized. Many false positive alerts relate to NOT utilizing the route of administration (e.g. for topicals). Included in drug-drug interaction checking for non-prescription medication orders include: All medication orders (prescription and non-prescription) that are 1) active or on the un-issued for the user placing the order, 2) have start dates prior to or equal to that of the order being placed

Require implementation of customization tools (e.g. Medical Logic Modules or knowledge base override tables) to allow institution-specific sorting or filtering of alerts based on patient specific information, thus reducing the number of false positive alerts. This solution requires a CIS architecture change therefore consider for 2008 or 2009.

The application should allow customers the ability to define how all medication conflicts will be presented during the medication order process. Customers will be able to define the presentation of specific conflicts (i.e. a specific drug-drug interaction) for six different categories of medication ordering, including 1) new prescriptions, 2) new non-prescriptions, 3) prescriptions reordered by the same user who originally ordered them, 4)

non-prescriptions reordered by the same user who originally ordered them, 5) prescriptions reordered by a different user than who originally ordered them, and 6) non-prescriptions reordered by a different user than who originally ordered them.

Additional capabilities should be created to take the dosing SIG into consideration for triggering interactions as many interactions have dose thresholds.

Also time/date stamp information is relevant to some interactions that may occur earlier in treatment (e.g. enzyme induction) versus those interactions that may occur after therapy is even discontinued. Medications with long half lives or with prolonged pharmacological effects (these medications should have an identified lag time specified in the dictionary tables indicating the time period (in hours) that the medication) will continue to be checked for drug-drug interactions past discontinue or expiration date.

Additional capabilities should be created to take a patient problem list and utilize the active conditions (as SNOMED-CT codes) as part of the checking algorithm for drug interactions as conditions (e.g. congenital QT prolongation) serve as predisposing factors for interactions.

IF-4.3.5
Criteria: The system shall provide the ability to set the severity level at which drug interaction warnings should be displayed.

Comment: Allow customization of severity level dependent upon patient-specific factors such as age and co-morbidities.

IF-4.3.6
Criteria: The system shall check for duplicate therapies by pharmaceutical class and alert the user at the time of medication ordering if such exist.

Comment: The system should provide customization features that include the ability to designate how many drugs from each therapeutic class would be considered an unintended therapeutic overlap. Customization capabilities should also include the ability to suppress certain overlap alerts completely; or suppress for certain types of orders such as for PRN orders (multiple prn pain meds order or laxatives order should not trigger therapeutic overlap alerts); suppress overlap alerts for orders that exist within an order set (which by definition is intended).

IF-4.3.7
Criteria: The system shall provide the ability to document reasons for overriding a drug interaction warning.

Comment: Override reasons should be available from a coded pick list

IF-4.3.8
Criteria: The system shall check for interactions between prescribed drugs and food detailing changes in a drug's effects caused by food (including beverages) consumed during the same time period.

Comment: CONSUMED FOODS do not currently exist in a standard coded terminology structure for EHR implementation, which makes it impossible to have alerts triggered by specific foods. Drugs do have known food interaction and this information should be made available upon demand or passively displayed as reference information.

IF-4.3.9
Criteria: The system shall provide alerts indicating to the prescriber that certain lab test results may be impacted by a patient's medications.

Comment: Drugs and labs have a complicated relationship that needs to be described here in order for CIS to provide different types of functionality. For instance there are labs that are necessary for monitoring efficacy endpoints. Conversely, some labs are utilized to monitor for potential toxicity. Additionally, there are labs that need to be assessed and monitored as they infer increased potential drug toxicity risk.
CIS should provide the ability for specified lab results encoded by LOINC to be available – along with date stamp inclusion criteria (retrieve serum creatinine results within last 7 days) along with viewing of results in various sort orders including chronological.

IF-4.3.10
Criteria: The system shall allow the prescriber to document a reason for discontinuing the medication

Comment: If reason for discontinuation is intolerance-related, then system should facilitate the intolerance documentation (described above)

IF-4.3.11
Criteria: The system shall provide the ability to check whether a medication being prescribed has been noted to be ineffective for the patient in the past, and alert the user at the time of medication ordering if noted ineffectiveness exists.

Comment: For ineffective drug also include optional fields for route, source of information, comments and level of certainty. Priority should be High for Provider, Patient and Quality Organization.

IF-4.3.12
Criteria: The system shall provide drug-disease interaction alerts.

Comment: SNOMED-CT encoded problem list (constrained to the CLINICAL FINDINGS and Procedures categories) should trigger disease contraindication warnings. ICD9cm and ICD10 (after 2009) are billing code sets that will have mapping to SNOMED-CT so that they also should be able to trigger disease warnings. A major issue here is that only active patient conditions (recent neurosurgery; GI bleed 1 week ago) should be used in the checking algorithms

IF-4.3.13
Criteria: The system shall provide the ability to display, on demand, potential interactions on a patient's medication list, even if a medication is not being prescribed at the time.

Comment: none

IF-4.3.14
Criteria: The system shall provide the ability to view the rationale for a drug interaction alert.

Comment: A minimum requirement is reference citation. Evidence-based ratings indicators do not really work with medical literature regarding warnings.

IF-4.3.15
Criteria: The system shall provide the ability to check for potential interactions between a current medication and a newly entered allergy.

Comment: Please clarify here that checking for allergy or intolerance will occur BOTH when adding new orders/drugs to the medication profile or when new patient data are being added to allergen/intolerance history portion of the patient record. Allergy and intolerance checking is addressed in a separate criteria.

IF-4.4.1 to 3 Support for Provider -Pharmacy Communication

IF- 4.4.1
Criteria: The system shall provide electronic communication between prescribers and pharmacies or other intended recipients of the medication order.

Comment: The system will provide medication order data to medication order dispensing technologies (i.e. robotics and controlled access cabinets), medication administration technologies (bar code eMAR, eMAR, RFID, and IV Smart Pumps.

The system will provide CCOW access to current medication orders based on secure patient context protocols.

The system will provide real time interfaces to enterprise receiving systems via HL7 interfaces using standardized code content.

The system will provide real time or batch interfaces to internal databases and receiving systems, including electronic patient records.

IF – 4.4.2
Criteria: The system shall electronically communicate from the prescriber to the pharmacy an initial medication order as well as changes to or renewals of an existing medication order.

Comment: The high patient safety risk associated with communicating non-standard content is huge. This leaves each communication at risk to be interpreted correctly by the receiving system.

Without content using coded standards, the system will provide functionality to accept various coding standards for dose unit of measure, schedule/frequency / dose form / and additional outpatient comments.

The system will be able to pass unique identifiers of medication orders between systems appropriately, to support the ability to modify or renew medication orders. Both systems need to track the modifications and renewals.

The system will be able to audit all modifications and renewals appropriately, and ensure that the appropriate action is clearly identified to the receiving system. Any failure in communication must be identified to the sending or receiving system in a timely manner.

This requirement was taken directly from the outpatient medication requirements. The handshaking between prescriber and the pharmacy for inpatient order is significantly greater than the handshaking for ambulatory prescribing. This is primarily due to the need to coordinate the order verification, medication preparation and medication delivery with the physician, and nurse and acute therapy requirements of the patient. Therefore this requirement requires significant expansion and overlaps with many of the requirements listed in other sections.

IF – 4.4.3
Criteria: The system shall capture any acknowledgements, prior authorizations, renewals, inquiries and fill notifications provided by the pharmacy or other participants in the electronic prescription.

Comment: The system will be able to provide the alert and provider response to questions between systems – free text may be appropriate.

There is a huge challenge between systems with different knowledge bases and clinical support alerts being generated according to enterprise policies. That is why the entire content of the alert and the provider response MUST be provided to the receiving systems.

There are many types of communications that occur in an inpatient environment between caregivers that needs to be addressed in this section. The workflows in an inpatient environment are significantly more complex and varied than in an outpatient environment. Therefore this section needs expansion to support these workflows. Specific workflows exist with regards to IV therapy, high alert medications, non-formulary medications, Stat medications and support of medications in the ED, OR, critical care areas as well as medications administered in associated ambulatory clinics.

IF-5.1.1 to 8 Support for Medication and Immunization Administration

IF-5.1.1
Criteria: The system shall present information necessary to correctly identify the patient and accurately administer medications and immunizations including patient name and medication name, strength, dose, route and frequency.

Comment: For best functionality the same Rx data elements and Rx data element attributes (e.g. data type, character length, etc.) should exist in all systems (CPOE, RxIS, and Point-of-Care). HL7 or NCPDP must set the standards for Rx data elements and Rx data element attributes. This standard must accommodate the most complicated and sophisticated prescribing such as Compounded and Extemporaneous items, IV admixture, TPN, PCA, IV Chemotherapy, etc. Uniform Rx data elements are necessary to prevent Rx data from being lost in translation as the Rx data moves across interfaces. Simple things like different frequency definitions in the pharmacy system and point-of-care system can result in miscommunication between nursing and pharmacy that can lead to medication errors. It is not uncommon for dosing frequencies such as once a week; give only on specific weekdays, three times per week, q72h, and one-time frequencies to be interpreted differently by these systems, even when these systems are provided by the same vendor. Development of consistent Rx data elements and attributes across systems (CPOE, RxIS, POC) should be a HIGH priority for CCHIT, HITSP and JCAHO, as this is a serious patient safety issue.

IF-5.1.2
Criteria: The system shall alert providers to potential administration errors such as wrong patient, wrong drug, wrong dose, wrong route and wrong time as it relates to medication and immunizations administration.

Comment: This functionality already exists in systems with an electronic MAR (eMAR) and bedside barcode medication administration systems. Consider changing availability and compliance to 2007.

Point-of-care systems should also allow care givers to retrieve an image and or imprint information to reduce wrong drug errors.

IF-5.1.3
Criteria: The system shall alert providers to potential medication administration errors at the point of medication administration

Comment: System to include reason for not given or late med so that when administrative reports are run can better identify problem, (Pt off floor, No IV access, etc.).

This functionality already exists in system with eMAR and bedside barcode medication administration. Consider changing availability and compliance to 2007.

System should allow administrative reports to be customized including IF-THEN logic on variables. Consider adding this functionality to the 2008 criteria.

IF-5.1.4
Criteria: The system shall provide the ability to capture all pertinent details of the medication administration including medication name, strength, dose, route time of administration and administrator of the medication

Comment: This functionality already exists in system with eMAR and bedside barcode medication administration. System shall also document mishaps such as pt refused meds, vomited meds, etc. Consider changing availability and compliance to 2007.

The system shall record the medication NDC number or other ID of the drug actually administered to the patient. This data shall be stored in the eMAR database and not displayed on the eMAR. This data is important for drug recalls and other legal /regulatory purposes. Consider adding this functionality to the 2008 criteria.

IF-5.1.5
Criteria: If required by the EHR user's scope of practice, the system shall capture the administrator of the immunization and the immunization information identified in DC.8.2, Conformance Criteria #3 details, including date, type, lot number and manufacturer.

Comment: This information can currently be captured in a comment field in eMAR systems, but it is not codified and not easily searchable. Ideally, the system will store information in EHR for use at future admissions and classify immunization as already given. This functionality requires the EHR to have a standardized Rx data model (See comments on IF-5.1.1). This is important patient safety information; discrete immunization data elements should be required criteria for 2008.

IF-5.1.6
Criteria: The system shall generate documentation of medication or immunization administration as a by-product of verification of patient, medication, dose, route and time.

Comment: This functionality already exists in system with eMAR and bedside barcode medication administration. Consider changing availability and compliance to 2007.

IF-5.1.8
Criteria: The system shall suggest alternative administration techniques based on age, developmental stage, weight, physiological status, mental status, educational level, and past physical history of the patient.

Comment: This functionality could be provided with an HL7 Arden Syntax based clinical rules engine. These rules engines have been commercially available from HIT vendors (Siemens, McKesson, etc.) since the 1990s. The prerequisite is a Patient Problems List with codified problems and conditions (see comments on IF-2.4.1 for details).

IF-5.2.1 to 3 Support for Medication and Immunization Recommendations

IF-5.2.1
Criteria: The system shall present recommendations for medication and immunization regimens based on findings related to the patient's age or diagnosis, including Tetanus, Pneumonia vaccine and Influenza vaccine.

Comment: This requirement is broad and vague. We would recommend that the system be specific to the medications and immunizations. An example might be the Beers criteria for drugs not to be used in patients over 65 years of age or the CDC guidelines for pneumococcal vaccine. Otherwise measuring these criteria will be subjective and difficult.

System scans each pt at admit for standard immunizations with recorded dates and reports those immunizations not already given.

CIS systems equipped with a HL7 Arden Syntax clinical rules engine could provide hospital designed recommendations for dosing, alternative therapy, and monitoring, based on lab results, current meds, allergies, vital signs, and other point-of-care findings. Recommendations based on diagnosis and the problem list requires at least local standardization of terms. Ideally, diagnosis and problem list will use an HL7 standard vocabulary. Consider changing priority to High, and changing availability and compliance to 2008.

Problem list identifiers encoded in SNOMED can be implemented with drug indications links that answers the question- what are drug to treat?

IF-5.2.2
Criteria: The system shall present alternative treatments in medications on the basis of cost or formularies.

Comment: Need capability to manage inpatient formulary and also have access to outpatient formularies for discharge medication options.

IF-5.2.3
Criteria: The system shall present suggested lab monitoring as appropriate to a particular medication

Comment: In addition to labs include all type of diagnostic monitoring such as baseline EKG before starting certain medications. Linking directing to ordering of the recommendations should be considered as criteria as well.

This functionality already exists in CIS equipped with HL7 Arden Syntax rules engines. Consider changing availability and compliance to 2007.

Comment: Drugs and labs have a complicated relationship that needs to be described here in order for CIS to provide different types of functionality. For instance there are labs that are necessary for monitoring efficacy endpoints. Conversely, some labs are utilized to monitor for potential toxicity. Additionally, there are labs that need to be assessed and monitored as they infer increased potential drug toxicity risk

CIS should provide the ability for specified Lab results encoded by LOINC to be available – along with date stamp inclusion criteria (retrieve serum creatinine results within last 7 days) along with viewing of results in various sort orders including chronological.

IF – 5.3.1 to 6 Support for Patient Specific Dosing & Warnings

Identify and present appropriate dose recommendations based on known patient-conditions and characteristics at the time of medication ordering

IF-5.3.1
Criteria: The system shall provide the ability to identify an appropriate drug dosage min-max range, for a single dose based on age (pediatric, adult, geriatric) specific for each known patient.

Comment: Please clarify what is meant by a single dose ; there are several types of dosing decision support that may be presented to an enduser: 1) executable drug orders that are in a complete SIG format (500mg oral tablet q12hours); 2) orders that need calculation and rounding (5mg/kg oral solution q8hours); and reference information in a daily dose range format (e.g. 2-5 gm/day divided in two to three doses for 7 to 10 days) The system will need to be able to calculate age in days (from either a birth date or age in years etc.) in order identifier any of the above patient-specific dosing information.

Population based min-max dosage range checking for a single dose and daily dosage based on age (pediatric, adult, geriatric) is already available in most pharmacy systems and may already be available in some CPOE systems. Consider changing availability and compliance to 2007.

IF-5.3.2
Criteria: The system shall provide the ability to identify an appropriate drug dosage based upon changes in criteria such as weight, renal and hepatic status.

Comment: Please clarify what is meant by changes in criteria. At a minimum when drugs are initially ordered, when there are order changes, or when drugs are reordered (e.g. renewed or rewritten for transfer)- these three parameters should be (re-)considered.

Weight, renal and hepatic function parameters can change over time, but is it intended that the system will detect a clinically significant change (weight up or down; renal/hepatic improve-worsen) and then the system will identify new drug dosing recommendations for current medications? That is if sequential weight/date information for a given patient is known, it is expected that the system will detect a significant change in weight and then perform appropriate drug dose re-calculations.

Renal function may be expressed in several ways within patient data (results or problem list or other). An estimated creatinine clearance (ml/min) Stevens LA, Coresh J, Greene T, Levey AS. Assessing kidney function--measured and estimated glomerular filtration rate.N Engl J Med. 2006 Jun 8;354(23):2473-83; a SNOMED-CT encoded problem that reperesents either acute or chronic renal impairment ; an impairment indicator consistent with one of five stages of kidney function as described by the National Kidney Foundation http://www.kidney.org/professionals/kdoqi/guidelines_ckd/p4_class_g2.htm

Also, have parameter set for time limitation on information used. If the information is too old a reminder for a new weight or appropriate lab test is displayed.

Consider changing the priority to High for Providers. This functionality is already available in the HL7 Arden Syntax based rules engines currently available from McKesson and Siemens and has been commercially available since the 1990s. Arden rules or Medical Logic Modules (MLMs) can be triggered upon storage of patient data such as a serum creatinine. The MLM can automatically calculate a creatinine clearance

(CrCL) and compare it to a past CrCl, and if a threshold is exceeded it can trigger dosing decision support from a knowledge base or another MLM for renally cleared drugs.

IF-5.3.3
Criteria: The system shall provide the ability to automatically alert the provider if the ordered dose is beyond the min-max range.

Comment: There are several dose checks to be performed that can be more explicitly stated here– there is the single dose check and the total daily dose check (or other amount per time ; e.g. 1 gram every 21 days). Single dose checks are especially important for weight-based drug dosing.

The system will need to take SIG orders that have interval/frequency ranges and perform calculations for total daily dose (e.g. 500mg po q4-6hours prn fever Temp.>101F) daily dose would be 3000 mg/day)

The system will need to sometimes perform additional units conversions and weight calculations with SIG orders (e.g. 500mg q12hours), to be able to check against weight-based daily dose range (2-5 gram/kg/day)

No mention is made explicitly mentioning dose interval/frequency checking or duration of therapy range checking.

Special dose check rules for Ordering or Bedside administration should be made available for special cummulative single ingredient dose checking across several medication formulation orders (e.g. cummulative acetaminophen dose/day in orders for Tylenol #3 prn added to Non-Asprin Bayer and Vicodin). Also, a few drugs need life-time dosing (chemotherapy).

Implementation to include electrolyte calculations- checks for IV solutions (e.g TPNs and others) where several forms of the same ion maybe ordered (Potassium, Calcium etc.)

IF-5.3.4
Criteria: The system shall provide the ability for the provider to override a drug dosage warning.

Comment: Override should be accompanied by alert acceptance capabilities with order edit functionality (not just cancel order and start over options).

IF-5.3.5
Criteria: The system shall provide the ability for provider to document reasons for overriding a drug alert or warning at the time of ordering.

Comment: Overrides need to record provider, time and date and pass with order to pharmacy system.

Override reasons should be selected from a picklist to allow for report generation later. Reasons for exceeding the maximum may include 1)consultant recommendation ; 2)disease severity warrants higher dosing ; 3)condition refractory to lower dosing ; Reasons for under range dosing might include 4) renal impairment (when this reason selected should include the capability for the system to up date the patient problem list to include this new renal impairment assessment).

IF-5.3.6
Criteria: The system shall transmit documented reasons for overriding a drug alert to the pharmacy or any other intended recipient of the electronic order by permanently attaching the override reasons to the electronic copy of the order.

Comment: It is imperative that the system have report generation capabilities in order to easily review alert override data.

NEW CRITERIA Suggestion:
The system shall check for Beer's drug list in all patients over 65 years of age and should allow for enduser customization of this list of drugs (add/deletes) as well as the severity of warning and message.

IF-5.4.1 to 4 Support for Monitoring Response Notifications Regarding a Specific Patient's Health

Support for Monitoring Response Notifications Regarding a Specific Patient's Health
In the event of a health risk alert and subsequent notification related to a specific patient, monitor expected actions taken and execute follow-up notification if they have not.

IF 5.4.1
Criteria: The system shall present specific actions to be taken at the patient level for a health risk alert

Comment: The system will help identify patients that are been administered drugs that have urgent health risk warning (e.g. FDA MedWatch sporadic report recently for Gleevec and CHF) and present recommendations for assessing the individual patient's risk for the health alert.

These specific actions should be linked to order entry.

IF-6.2.1 to 6.2.8 Support internal and external epidemiological investigations

IF-6.2.3
Criteria: The system shall provide the ability to use any demographic or clinical information as criteria for aggregation

Comments: Add geographic data. For in public health the location patterns may be highly important. (i.e., Map by county.)

IF-6.2.4
Criteria: The system shall present aggregate data in the form of reports for external use.

Comments: System must be able to de-identify data to stay HIPAA compliant. High HIPAA Priority.

IF-6.2.6
Criteria: The system shall present aggregate data in an electronic format for use by other analytical programs.

Comments: Before data can be shared it must be scrubbed of pt identifiers. High priority for HIPPA.

IF-6.2.7
Criteria: The system shall provide the ability to derive statistical information from aggregate data.

Comments: Add after statistical information “and standard epidemiological parameters” In public health relative risk and absolute risk are commonly calculated. Data needs to be stored with a structure that can be used in analyses. Be able to show trends in the data.

IF-6.3 Support Remote Healthcare Services

IF-6.3.1
Criteria: The system shall support the capture of patient data from remote devices and integrate that data into the patient's record.

Comments: Multiple methods of matching one set of patient data to another are required since not all data sets contain the same identifiers and some data may be missing. Also, there needs to be an ability to match on at least two identifiers as some people have the same name or birth date. Sometimes numbers are transposed in MRNs or SSNs.

IF-6.4 Support for Notification and Response

IF 6.4.2
Criteria: The system shall provide the ability to prepare a response notification to the care providers or care managers.

Comments: Add “in a timely fashion.” If there is a public health outbreak care providers and care mangers need to know as soon as possible. Have computer alert appropriate staff when certain conditions are met.

IF-6.4.5
Criteria: The system shall provide the ability to notify patients, directly or indirectly, who are described by the health risk alert

Comments: Some types of notifications may frighten the pts. With each notification include a comment field for additional information about the problem and a phone number where further information may be obtained.

IF-6.5.1 Outcome Measures and Analysis

IF-6.5.1
Criteria: The system shall provide the ability to define report formats for the export of data. This formatted data could be viewed, transmitted electronically or printed.

Comments: System needs proper security so that patient level information is shared with only those who are properly trained and need to know it. High priority HIPAA.

IF-6.5.2
Criteria: The system shall provide the ability to define presentation filters that are specific to the patient demographics

Comments: In Public Health and Epidemiology data is commonly adjusted for confounders and not simply filter. This allows for information in the data to be used to generate a more specific answer.

IF-6.6.1 to 2 Communication with Medical Devices

GENERAL COMMENT --
Communication with medical devices should be bi-directional where appropriate. The only "human" interaction with these devices should be on/off switch or sample collection

(blood glucose monitors). In particular, medication pumps should be able to query the clinical information system for the correct flow rate based upon the nurse scanning the medication and pump at the bedside. This will minimize errors in the manual programming of the pumps and eliminate the need for extensive training programs for nursing personnel related to the multiple programming routines for the different brands of pumps that might appear on their unit.

The communication should be bi-directional. One of the problems with these devices is keeping the various libraries up-to-date. Also, the complexity in programming said pump by the nursing staff. If the IV label scan was order number, the pump should be able to send a query for the HIS to provide a flow rate. This would also allow a rate change in the HIS to automatically to be transmitted to a pump. A nice feature when the patient is off the unit.

The only "human" interaction with a medical device should be an on/off switch...the organization's ordering system followed by a series of validation and verification steps in the pharmacy and point of care systems should run the device.

Standardized data elements for continuous IV parameters like infusion rate, etc. might allow infusion pumps to be controlled from the CIS point-of-care system (POC). This might also allow Pharmacy information system to automatically query the IV infusion rate and volume remaining from the POC for scheduling IV label batches in the pharmacy.

6.6.1
Criteria: The system shall provide the ability to collect accurate electronic data from medical devices.

Comment: Information shared should be discreet data elements that allow for trending, reporting and automated analysis. While many of the vendors already do this, the key here is that it needs to be discreet data and not some text translation. We need to be able to analyze the data.

6.6.2
Criteria: The system shall provide the ability to present and share information collected from medical devices as part of the medical record as appropriate

Comment: Information should be in the form of discrete data elements. Again, received and stored as discrete data will allow for trending of data.

6.6.3
Criteria: The System will support a method to receive notification from an external medical device (service location (ADS, Robot, etc) that the designated location is unable

to supply a called for medication. The System will call for the next location in the hierarchy to dispense the required medication. For Example: An ADS drawer has failed, the medication is not accessible.

Comment: This notification should consider not only the medication, but also the package size (particularly with IVs fluids). If possible, different strengths should be considered such as the ability to provide 2 x 200mg tablets for a 400mg tablet.

6.6.4
Criteria: The system will support receiving an acknowledgment response from an external medical device after sending a message

Comment: This type of response is called an "ack". This should also require the receiving of not-acknowledgment responses ("nack") and that communication should be continued until an "ack" message is received.

Proposed Criteria for 2007 Certification of Inpatient Interoperability

II-3.1 to 8 Medication Management - From Outpatient Setting into Emergency Center Care or Admission for Inpatient Care

NOTE: COMMENTS ARE THE SAME FOR RECEIVING MEDICATION AND ALLERGY HISTORY FROM ANY SOURCE.
General: The major challenge is that each application supports the data in different data architectures and content standards. An interim phase must be implemented – for example using standardized data labeling codes, then moving to standards in the data content for each data label.

II - 3.1
Criteria: Receive outpatient Medication and Allergy history form Pharmacy (directly) or via intermediary network (e.g. SureScripts, RxHub, etc)

Comments:

Comment on Allergen History: The system will support transmission of the entire allergen history with each medication order. Some systems will do a total replacement and others will provide an update when the data is received.

The systems will provide support for allergens and intolerances as separate entities.

The system will require allergen data entry for every medication order, even if the only update is the change of allergen review date and the responsible party.

The systems need to support coded allergen data fields, including SnoMed.

The system will prevent deletion of allergen data and maintain de-activation of allergen data.

The system will require that allergen data is transmitted with every medication order, including new allergens, modifications, and de-activations.

The systems will provide the last update date and responsible party for allergen data.

The system will require allergen reactions, severity, source, reliability of data.

The systems will appropriately support modifications to the Allergen history and consider these new updates according to the modification date .This data shall be communicated. This data will be available for the HL7 communication concepts of patient visit re-assignment and patient merge.

The systems will be able to support independent update of the Allergen history as a standalone message without a Medication order event needing to occur.

Comments on Medication history: The system will support transmission of a clearly defined time frame of the medication history with each medication order. Some systems will do a total replacement and others will provide an update when the data is received.

The system will support the receipt of Medication history in a clearly defined format. Until standardized content codes and labels for the data items, the data must be clearly communicated. .

The systems will support the current regulatory data requirements on Medication reconciliation, thus appropriately supporting the variances in enterprise implementation of the regulatory requirements.

The systems will appropriately support modifications to the Medication history and consider these new updates according to the modification date. This data shall be communicated. This data will be available for the HL7 communication concepts of patient visit re-assignment and patient merge.

The systems will be able to support independent update of the Medication history as a standalone message without a Medication order event needing to occur.

II 3.2
Criteria: Receive outpatient Medication and Allergy history from Physicians office/clinic EMR.

Comment: AS ABOVE

II 3.3
Criteria: Receive outpatient Medication and Allergy history from PBM (directly) or via intermediary network (e.g. Sure Scripts, RxHub, etc)

Comment: AS ABOVE

II 3.4
Criteria: Receive outpatient Medication and Allergy history from Health Plans

Comment: AS ABOVE

II – 3.5
Current Criteria: Receive / import medication history from a PHR

Comment: AS ABOVE

II 3.6
Criteria: Receive outpatient Medication and Allergy history from RHIO/Network

Comment: AS ABOVE

II 3.7
Criteria: Receive outpatient Medication and Allergy history from other institution (Hospital, Nursing home, Rehab center, etc)

Comment: AS ABOVE

II 3.8
Criteria: Receive outpatient Medication and Allergy history from other sources (State Medicaid, home health/nursing agencies, public health, etc) via direct feed or intermediary

Comment: AS ABOVE

II 3.9 to 3.13 Medication Management – Within Inpatient Care Setting

GENERAL:

The lack of clearly defined regulations on Range Dose and Range Schedule orders creates workarounds in every system. The communication of the intent of the Medication order is at risk with every event. The systems have different workarounds, which are not able to be safely and reliably translated appropriately through interface engines, mapping, or other programming. Subsequently, many institutions do not have the internal information expertise to manage the inherent challenges.

The systems will provide appropriate support for the clearly defined JCAHO policies on range dose medication orders.

- CASE: Provider uses the system to generate an order “rug A one to two tabs q 4 hrs”
- The challenge is for the systems to communicate the order without increasing the patient safety risk.

- One system may interpret the order into two separate orders: Drug A one tab q 4 hrs and Drug A two tabs q 4hrs , thus creating a risk for two MAR or eMAR entries and duplicate dose being administered. It also eliminates the Dose Range checks within the system with two separate orders.

- The systems will provide appropriate support for the clearly defined JCAHO policies on range schedule medication orders.

- CASE: Provider uses the system to generate an order "Drug A one tab q 4-6 hrs"

- The challenge is ensuring that the systems to communicate the order without increasing the patient safety risk.

- One system may interpret the order into two separate orders: DrugA one tab q 4 hrs and Drug A one tab q6 hrs, thus creating a risk for two MAR or eMAR entries and duplicate dose being administered. It also eliminates the Dose Range checks within the system with two separate orders.

II 3.9
Criteria: Send Inpatient Medication orders and allergy information to inpatient pharmacy system for verification between systems by same vendor OR between systems by different vendors.

Comment: The system will support transmission of the entire allergen history with each medication order. Some systems will do a total replacement and others will provide an update when the data is received.

The systems will provide support for allergens and intolerances as separate entities.

The system will require allergen data entry for every medication order, even if the only update is the change of allergen review date and the responsible party.

The systems need to support coded allergen data fields, including SnoMed.

The system will prevent deletion of allergen data and maintain de-activation of allergen data.

The system will require that allergen data is transmitted with every medication order, including new allergens, modifications, and de-activations.

The systems will provide the last update date and responsible party for allergen data.

The system will require allergen reactions, severity, source, reliability of data.

The systems will appropriately support modifications to the Allergen history and consider these new updates according to the modification date. This data shall be communicated.

This data will be available for the HL7 communication concepts of patient visit re-assignment and patient merge.

The systems will be able to support independent update of the Allergen history as a standalone message without a Medication order event needing to occur.

II 3.10
Criteria: Dispense Medications – send orders to pharmacy "BOT"

Comment: none

II 3.11
Criteria: Dispense Medications – send orders to other automated dispensing equipment (Pyxis cabinets, etc)

Comment: The system will support HL7 interactive bi-directional interfaces between automated dispensing technologies and the applications. The system will support audit trails of the interface messages.

The system will support billing business options on the both the application and the automated dispensing equipment platforms.

II 3.12
Criteria: Dispense Medications – Bar coded identification of Medication and patient

Comment: The system will provide support for the RxNorm concept for each medication inventory item.

The system will provide flexibility for bar code support.

The system will provide support for the bar code content, including the NDC, the expiration date and the lot number. This will provide better patient safety for recall events.

The system will provide support for a large number of bar codes to be attached to a single medication inventory item (at the RxNorm level).

The system will provide automatic update functionality from commercial sources (knowledge bases, wholesalers) of both the NDC and the Pharma bar code on the medication at the item level.

The system will provide support for the calculation of different sizes creating the whole dose. For example, Prednisone 50mg can be calculated in many ways – and the system

must be able to support the scan of a number of variations of the dose to calculate the total dose appropriately.

The system will provide support for a single medication order for a dose not commercially available. For example, Warfarin 7mg, other wise the communication between the medication order entry system and the controlled access cabinets will be a newly created patient safety risk point.

II 3.13
Criteria: Inpatient Medication reconciliation between inpatient care settings: admission, critical care procedure units, surgery, etc

Comment: The system will provide Medication history.

The system will support transmission of a clearly defined time frame of the medication history with each medication order. Some systems will do a total replacement and others will provide an update when the data is received.

The system will support the receipt of Medication history in a clearly defined format. Until standardized content codes and standardized labels for the data items, the data must be clearly communicated,

The systems will support the current regulatory data requirements on Medication reconciliation, thus appropriately supporting the variances in enterprise implementation of the regulatory requirements.

The systems will appropriately support modifications to the Medication history, consider these new updates according to the modification date and communicate this data. This data will be available for the HL7 communication concepts of patient visit re-assignment and patient merge.

The systems will be able to support independent update of the Medication history as a standalone message without a Medication order event needing to occur.

II-3.14 to 3.18 Medication Management - Discharge to Outpatient Care or Transfer to Another Institution

II 3.14
Criteria: Send inpatient Medication history to Physicians office/clinic EMR

Comment: Codification of medication in RxNorm is essential for interoperability. Suggest that this be in for 2008.

II 3.15
Criteria: Respond to a query for Medication history send by a PHR and send inpatient Medication history to patient PHR
Comment: Codification of medication in RxNorm is essential for interoperability. Suggest that this be in for 2008.

II 3.16
Criteria: Send inpatient Medication history to RHIO/network

Comment: Codification of medication in RxNorm is essential for interoperability. Suggest that this be in for 2008.

II 3.17
Criteria: Send inpatient Medication history to other institution (hospital, nursing home, rehabilitation center, etc.)

Comment: Codification of medication in RxNorm is essential for interoperability. Suggest that this be in for 2008.

II 3.18
Criteria: Send inpatient Medication history to other sources (State Medicaid, home health/nursing care agencies, public health, etc.) directly or via intermediary

Comment: Unclear what an intermediary is? Please specify in criteria.

II-3.19 to 3.29 Medication Management – Send Prescriptions

II-3.19
Send an electronic prescription to pharmacy HL7 v2.x, NCPDP Script 8.1 (NEWRX)

Comment: Need clarification on the originating system/process for electronic prescription. This should include discharge prescriptions but delivery should be 2009 or later.

II-3.20
Criteria: Send electronic prescription to pharmacy including structured and coded SIG instructions NCPDP Script 11.1 not available yet

Comment: Needed support for discharge prescriptions to follow ePrescribing implementation.

II-3.21

Criteria: Respond to a request for a refill sent from a pharmacy NCPDP Script 8.1 (REFREQ, REFRES)

Comment: none

II-3.22
Send a cancel prescription message to a pharmacy NCPDP Script 8.1 (CANRX, CANRES)

Comment: Needed and should follow electronic prescribing implementations.

II-3.23
Respond to a request for a prescription change from a pharmacy NCPDP Script 8.1 (RXCHG, CHGRES)

II-3.24
Criteria: Send a query to verify prescription drug insurance eligibility and coverage X12 270/271/ CORE Phase I Rules

Comment: This would be useful functionality for discharge/ED prescriptions.

II-3.25
Criteria: Send a query for formulary information NCPDP Formulary and Benefit Standard Implementation Guide v1.0

Comment: This would be useful functionality for discharge/ED prescriptions.

II-3.26
Criteria: Send a query for Medication history to PBM or pharmacy and import Medication list into EHR NCPDP Script 8.1 (RXHREQ, RXHRES) / NDC codes

Comment: Support would be useful but source of profile information would need to be clear in the EHR. Passing this data forward from the EHR would only be acceptable if it is reconciled at the hospital.

II-3.27
Criteria: Receive Medication fulfillment history NCPDP Script 8.12 (RXFILL)

Comment: Information would be useful for ED and hospital admissions.

II-3.28
Criteria: Send outpatient electronic Prescription to PBM directly or via intermediary network (e.g. SureScripts, RxHub, etc.) HL7 v2.x, NCPDP Script 8.1 (NEWRX)

Comment: Would be helpful but should follow eRx implementation. (2009+)

II-3.29
Criteria: Send active inpatient Medication orders history and allergy info to other institutions (rehabilitation center, tertiary care center, nursing home, etc.) HL7 v2.x

Comment: May be useful but only reconciled information should be sent.