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Service Functional Model Specification - Decision Support Service (DSS)

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Project Lead and Editor

Kensaku Kawamoto: kawam001@mc.duke.edu
(Duke University)

Contributors

Brett Esler: brett@pencs.com.au
(Pen Computer Systems)

1 **Preface**

2 Notes to Readers

3 This document is the Service Functional Model (SFM) for the Decision Support Service, which is
4 specified under the Service Development Framework process under the auspices of the Healthcare
5 Services Specification Project (HSSP). Further context is given in the overview section below, but one
6 key point to note is that the SFM provides a Service **Interface** specification, NOT the specification of
7 a Service implementation. This is a critical distinction in terms of Service Oriented Architecture.
8 There could be many different ways of implementing all or part of the functionality to support the
9 behavior described in this specification.

10

11 Changes from Previous Release

12 This is the first public release of this document.

13

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16 during the development of this specification.

17 Clayton Curtis: Clayton.Curtis@va.gov (Veterans Health Administration)

18 Guilherme Del Fiol: Guilherme.DelFiol@intermountainmail.org (Intermountain Healthcare)

19 Robert Hausam: robert.hausam@theradoc.com (TheraDoc, Inc.)

20 Alan Honey: alan.p.honey@kp.org (Kaiser Permanente)

21 Robert Jenders: jenders@ucla.edu (Cedars-Sinai Medical Center/University of California, Los
22 Angeles)

23 David Lobach: david.lobach@duke.edu (Duke University)

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198 Note that sections of this document in <blue> indicate text that is consistent across HSSP specifications

1 Overview

1.1 Introduction and Scope

1.1.1 HL7-OMG Healthcare Services Specification Project (HSSP)

The Healthcare Services Specification Project (HSSP) (<http://hssp.wikispaces.com>) is a joint endeavor between Health Level Seven (HL7) (<http://www.hl7.org>) and the Object Management Group (OMG) (<http://www.omg.org>). The HSSP was chartered at the January 2005 HL7 meeting under the Electronic Health Records Technical Committee (TC), and the project was subsequently validated by the Board of Directors of both organizations.

The HSSP has several objectives. These objectives include the following:

- To stimulate the adoption and use of standardized “plug-and-play” services by healthcare software product vendors
- To facilitate the development of a set of implementable interface standards supporting agreed-upon services specifications to form the basis for provider purchasing and procurement decisions.
- To complement and not conflict with existing HL7 work products and activities, leveraging content and lessons learned from elsewhere within the organization.

Within the HSSP process, HL7 has primary responsibility for (1) identifying and prioritizing services as candidates for standardization; (2) specifying the functional requirements and conformance criteria for these services in the form of Service Functional Model (SFM) specifications such as this document; and (3) adopting these SFMs as balloted HL7 standards. These activities are coordinated by the HL7 Services Oriented Architecture SIG in collaboration with other HL7 committees, which currently include the Vocabulary TC and the Clinical Decision Support TC.

Based on the HL7 SFMs, OMG will develop “Requests for Proposals” (RFPs) that are the basis of the OMG standardization process. This process allows vendors and other submitters to propose solutions that satisfy the mandatory and optional requirements expressed in the RFP while leaving design flexibility to the submitters and implementation flexibility to the users of the standard. HL7 will be involved in the RFP creation and evaluation process.

It is important to note that the HL7 SFMs will focus on specifying the *functional* requirements of a service, while OMG specifications will focus on specifying the *technical* interface requirements of a service.

1.1.2 Context of this SFM within HSSP Process

As described above, the purpose of an HL7 SFM is to identify and document the functional requirements of services important to healthcare. Accordingly, this SFM seeks to define the functional requirements of a decision support service (DSS), which is a service that takes patient data as the input and returns patient-specific conclusions as the output. Once adopted as an HL7 standard, it is anticipated that this SFM will serve as the basis for one or more OMG technical specifications for decision support services.

1.1.3 Disclaimers

Please note the following disclaimers regarding this SFM:

- Examples are illustrative and not normative, unless otherwise specified. Specifically, the business scenarios in Sections 3 and 7 are meant to illustrate how a DSS *could* be used to meet

decision support needs, rather than how a DSS *should* or *must* be used. Also, the sample content provided in Sections 14 and 15 is also non-normative in nature.

- HSSP SFMs are not limited to the use of HL7 content as service payloads. However, each SFM must provide a mechanism to support the use of HL7 content as a semantic profile. Accordingly, this SFM supports the use of HL7 semantic constructs but does not preclude the use of non-HL7 content within service operations.

1.2 Guide to Readers

Table 1 provides a high-level overview of the sections of this SFM. This table also provides guidance on the relevance of individual sections based on the goals of the reader.

Table 1. Overview of SFM sections and relevance to readers based on their goals

SFM Section(s)	Description	Applicable to Readers with Following Goals		
		Obtain high-level understanding of how a DSS can be used to meet decision support needs	Obtain detailed understanding of how a DSS can be used to meet decision support needs	Understand SFM in order to issue or respond to OMG RFP for DSS technical specification
2.1. Description of the Proposed Service (p. 10) 2.2. The Reason Why the Service Specification is Needed (p. 17)	Provides a high-level overview of the capabilities of a DSS and why a DSS standard is needed	X	X	X
2.3. Structure of the Service (p. 19)	Provides an overview of the service interface and key constructs used by the service (e.g., semantic signifiers)	All sub-sections, except for 2.3.3.3, 2.3.3.4, and 2.3.4	X	X
2.4. Implementation Considerations (p. 27)	Outlines issues to be considered for implementation		X	X
3. Business Scenarios (Informative Content) (p. 28)	Illustrates how a DSS can meet decision support needs	X	X	X
4. Service Definition and Dependencies (p. 32)	Describes service definition principles used, provides summary of service interfaces, and outlines dependencies	X	X	X
5. Detailed Functional Model for each Interface (p. 34)	Provides a detailed specification of each service interface		X	X
6. Profiles (p. 56)	Describes the use of profiles and defines several profiles		X	X

SFM Section(s)	Description	Applicable to Readers with Following Goals		
		Obtain high-level understanding of how a DSS can be used to meet decision support needs	Obtain detailed understanding of how a DSS can be used to meet decision support needs	Understand SFM in order to issue or respond to OMG RFP for DSS technical specification
7. Use Scenario Interaction Details (Informative Content) (p. 60)	Elaborates on the business scenarios described in Section 3. Sequence diagrams provided.		X	X
8. The Services Framework Functional Model (p. 75)	Describes common, infrastructure-type functions and services that are being specified by the HSSP		X	X
9. Information Model and Semantic Binding Approach (p. 75)	Describes the overall HSSP approach towards the binding of information content to services		X	X
10. Recommendations for Technical RFP Issuance (p. 75)	Provides recommendations for issuing the RFP for an OMG DSS technical specification			X
11. Assumptions (p. 77)	Identifies assumptions made by the SFM		X	X
12. Glossary (p. 77)	Provides a glossary of terms used by the SFM	X	X	X
13. Appendix I: Relevant Standards and Reference Content (p. 80)	Outlines relevant standards and reference content		X	X
14. Appendix II: Sample Decision Support Services (Non-Normative) (p. 81)	Describes sample DSSs referenced in the business scenarios (Sections 3 and 7)		X	X
15. Appendix III: Reference Content for Business Scenarios (Non-Normative) (p. 116)	Provides non-normative content referenced in the business scenarios		X	X
16. Appendix IV: HL7 EHR Functional Model Traceability (p. 118)	Describes how a DSS could be used to support many of the CDS functions specified in the HL7 EHR functional model		X	

253 2 Service Overview and Business Case

254 2.1 Description of the Proposed Service

255 2.1.1 Business Purpose of the Specification

256 In recent years, research has emerged showing that the healthcare delivered in many industrialized
257 nations falls short of optimal, evidence-based care. In the United States, a recent nationwide audit
258 assessing 439 quality indicators found that American adults receive only about half of recommended
259 care,¹ and the U.S. Institute of Medicine has estimated that up to 98,000 Americans die each year as
260 the result of preventable medical errors.² In the United Kingdom, a recent retrospective analysis at two
261 London hospitals found that 10.8% of admitted patients experienced adverse events, of which 48%
262 were judged to be preventable and of which 8% led to death.³ Similarly in Australia, a review of
263 medical records from 28 hospitals identified adverse events in 16.6% of admissions, of which 51%
264 were deemed preventable and of which 4.9% led to death.⁴

265 One of the most promising strategies for addressing this crisis in care quality is the use of clinical
266 decision support (CDS) systems, which are systems that provide physicians and other healthcare
267 stakeholders with patient-specific assessments or recommendations in order to aid in clinical decision
268 making. Examples of CDS systems include outpatient systems that attach care reminders to the charts
269 of patients in need of specific preventive care services, computerized provider order entry (CPOE)
270 systems that provide patient-specific recommendations as part of the order entry process, and
271 laboratory alerting systems that page physicians when critical lab values are detected.

272 CDS systems can be highly effective at improving care quality and ensuring patient safety. In a recent
273 systematic review, for example, CDS systems possessing four critical features were found to
274 significantly improve clinical practice in 94% of randomized controlled trials.⁵ Despite these
275 promising results, however, the availability of decision support capabilities remains limited in most
276 health care facilities in the U.S. and elsewhere. Although many barriers contribute to this limited use
277 of decision support systems, one important barrier is the difficulty and cost associated with
278 implementing effective decision support systems.

279 As with other types of applications, a CDS system could be more easily implemented and maintained
280 if software services were available to provide functionality required by the application. **Table 2** lists
281 some of the services that may be useful for the implementation of a CDS system, including: (i) a
282 decision support service (DSS), which uses patient data to draw machine-interpretable conclusions
283 regarding patients; (ii) a common terminology service (CTS), which provides access to various
284 terminology operations; (iii) an entity identification service (EIS), which enables the identification of
285 entities (e.g., patients) across systems; (iv) a record locator and access service (RLAS), which
286 facilitates the retrieval of patient records across systems, and which also allows for fine-grained
287 queries for patient data; (v) a patient record update service (PRUS), which allows the service client to
288 update the patient record; and (vi) an electronic health record (EHR) action brokering service (EABS),
289 which permits the service client to invoke various actions within an EHR. Of note, the patient data
290 query service component of the RLAS, the PRUS, and the EABS comprise the primary services that an
291 EHR would need to implement in order to provide what is known as a virtual medical record (vMR)

¹ McGlynn EA, Asch SM, Adams J, et al. The quality of health care delivered to adults in the United States. *N Engl J Med*. 2003;348:2635-2645.

² Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 1999.

³ Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ*. 2001;322:517-519.

⁴ Wilson RM. The quality in Australian Health Care Study. *Medical Journal of Australia* 163:458-71, 1995.

⁵ Kawamoto K, Houlihan CA, Balas EA, Lobach DF. Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success. *BMJ*. 2005;330:765-772.

Service	Description	Example of Service Use by a CDS system
Decision Support Service (DSS)	Provides machine-interpretable, patient-specific assessments and recommendations given requisite data.	When a patient checks into an outpatient clinic, the clinic's EHR sends relevant patient data to the DSS, receives back the patient's care needs (e.g., overdue preventive care procedures, medication incompatibilities), and informs the clinician regarding those care needs.
Common Terminology Service (CTS)	Provides access to various terminology operations (e.g., translation of a code between vocabularies, identification of semantic relationships between codes).	When authoring a rule regarding beta-blocker use following a myocardial infarction, a knowledge engineer provides the CTS with the SNOMED CT code for the beta-blocker drug class and requests all SNOMED CT codes that are subsumed by (i.e., are descendants of) the provided code. The engineer also makes a request to the CTS to translate the SNOMED CT codes to FDA NDC codes. The SNOMED CT and NDC codes indicative of beta-blockers are used to determine whether a patient who has suffered a myocardial infarction is currently prescribed a beta-blocker.
Entity Identification Service (EIS)	Allows the service client to identify entities (e.g., patients) across systems.	When determining whether a patient is in need of an influenza vaccine, a CDS system associated with Health System A uses EISs to identify that the patient has a medical record number with the local health department, as well as with Clinic B. The CDS system provides these system-specific record numbers to the RLASs of the health department and of Clinic B, and the CDS system requests that the RLASs retrieve data on the influenza vaccination procedures the patient has received at these sites over the past year. Through this interaction, the CDS system is able to determine that the patient received a flu shot this year at the local health department. As a result, the CDS system correctly concludes that the patient is not in need of a flu shot.
Record Locator and Access Service (RLAS)	Allows the service client to locate and retrieve records for a patient across systems. Allows for fine-grained record retrieval (e.g., query for lab tests for a patient from the past 3 months with LOINC codes A, B, or C).	See example above for EIS.
Patient Record Update Service (PRUS)	Allows the service client to update a patient's record.	When the hematocrit is entered into the clinical data repository for a patient being treated in the hospital, a CDS system detects that the hematocrit is critically low and sends a page to the intern responsible for the patient's care. The CDS system makes a request to the PRUS to record into the clinical data repository the details regarding the alert (e.g., when it was sent, to whom it was sent, why it was sent).
EHR Action Brokering Service (EABS)	Allows the service client to request that the EHR performs pre-specified actions.	A clinician consults a decision support module in an EHR to decide on a medication regimen for a patient with hypertension. The CDS system determines that additional data are required to reach a conclusion. The CDS system makes a request to the EABS to collect the required data from the clinician; upon receiving the request, the EABS asks the clinician for the required information through the EHR user interface. The EABS then returns the information to the CDS system so that a conclusion can be reached.

293 interface.⁶ Currently, specifications for the CTS, EIS, and DSS are being actively worked on by
294 members of the Healthcare Services Specification Project (HSSP). Also, the HSSP Retrieve, Locate,
295 and Update Service (RLUS) encompasses the functionality of the RLAS and PRUS.

296 All of the services just described facilitate the implementation of a CDS system, as they allow a CDS
297 system to fulfill many of its functional requirements by making requests to existing services.
298 Specifically with regard to the Decision Support Service (DSS), the service allows a CDS system to
299 reach conclusions regarding a patient by making requests to one or more DSSs. Furthermore, the
300 service allows a single DSS to simultaneously fulfill the patient evaluation requirements of multiple
301 decision support applications. Because the specification and updating of machine-executable decision
302 logic represents one of the most expensive aspects of developing and maintaining a decision support
303 system, this arrangement could significantly reduce the effort required for a CDS system
304 implementation. This reduction in the effort required to implement and maintain a CDS system is the
305 primary business purpose for the DSS. It is hoped that the DSS standard will facilitate the more
306 widespread adoption of CDS systems, which in turn should result in higher quality care and improved
307 patient safety.

308 **2.1.2 Description of Functional Capabilities in Business Terms**

309 A DSS can be conceptually understood as the guardian of one or more modules of medical knowledge,
310 wherein each DSS knowledge module is capable of utilizing coded patient data to arrive at machine-
311 interpretable conclusions regarding the patient under evaluation. The scope of a typical DSS
312 knowledge module is the assessment of a single patient in a specified topic area. The topic area may
313 be narrow (e.g., the need for a glycated hemoglobin test for a patient with diabetes) or broad (e.g., the
314 existence of contraindications to any medications prescribed or about to be prescribed for a patient).

315 A DSS is used by a DSS client, which is alternatively referred to as a “client” or as a “client system” in
316 this SFM. A DSS client is any external entity that interacts with a DSS to obtain its services.
317 Examples of DSS clients include a DSS query system used by an engineer to find and explore
318 knowledge modules at design time (see Section 3.2.1) or an operational CDS system that interacts with
319 a DSS at run-time.

320 When requesting a patient evaluation, a client CDS system specifies the knowledge modules to use for
321 the evaluation, and the CDS system also submits the patient data required by the knowledge modules.
322 In return, the DSS returns inferences regarding the patient in a format that has been pre-defined for that
323 knowledge module. For example, an online immunization registry might submit data on a patient’s
324 allergies and on her past immunizations to a DSS and request that the patient be evaluated using the
325 service’s immunization knowledge module. In return, the DSS might return a list of the vaccines for
326 which the patient is ineligible due to contraindications, a list of the vaccines for which the patient is
327 up-to-date, and a list of the vaccines for which the patient is due.

328 Of note, a DSS knowledge module may or may not have a one-to-one correspondence with an
329 underlying computational construct. For example, the immunization knowledge module just described
330 may be implemented using one computational construct (i.e., a single construct that checks for the
331 need for a number of vaccines) or multiple computational constructs (e.g., one construct that checks for
332 the need for a flu vaccine, a second construct that checks for the need for a pneumococcal vaccine,
333 etc.).

⁶ Johnson PD, Tu SW, Musen MA, Purves I. A virtual medical record for guideline-based decision support. *Proc AMIA Symp.* 2001;294-8.

334 **Table 3** provides examples of the types of inferences that could be made by a DSS.

335 **Table 3.** Example inferences that could be made by a DSS

Sample Evaluation Input	Sample Evaluation Output
Patient age, gender, past health maintenance procedures	List of health maintenance procedures due or almost due
Medication identifier, age, gender, weight, serum creatinine level	Recommended maximum and minimum doses for medication given patient's estimated renal function
Age, gender, co-morbidities, chief complaint	Admission order set in HL7 format
Insurance provider, data relevant to prescription	Whether the prior authorization criteria for prescribing the medication are met

336 In order to acquire patient evaluations in this manner, a client must be able to obtain several
337 supplemental pieces of information from a DSS. These supplemental information needs consist of the
338 need to (i) identify the knowledge modules that could be used to meet client needs; (ii) know what
339 patient data must be submitted to the DSS in order to obtain an accurate evaluation; and (iii) know the
340 meaning and format of any results that will be returned by the DSS following a patient evaluation.
341 **Table 4** lists these supplemental client information needs; a brief description is also provided for the
342 DSS operations that meet these information needs.

343 **Table 4.** Supplemental information required for obtaining patient evaluations using a DSS, and brief descriptions
344 of the service operations that provide the required information

Supplemental Information Need	Operation Providing Required Information	Description of Service Operation
Identification of knowledge modules meeting client needs	Find Knowledge Modules	Identifies the service's knowledge modules that meet client search criteria. It is anticipated that the search for appropriate knowledge modules will generally occur at design time (see business scenario in Section 3.2.1.2).
Information on the data required for evaluating a patient using the specified DSS knowledge modules	Get Knowledge Module Data Requirements	Explicitly specifies the data required for evaluating a patient using the selected knowledge modules
Specification of the meaning and format of the patient evaluation results that will be returned by the specified DSS knowledge modules	Get How Knowledge Module Evaluation Results Will be Returned	Provides a description of the specified knowledge module, including the content and structure of the results that will be returned when the module is used to evaluate a patient

345 Through the use of these supplemental operations, a service client is able to identify the knowledge
346 modules that are available from one or more DSSs for meeting the service client's CDS needs.
347 Furthermore, the service client is able to determine what data are needed for requesting a patient
348 evaluation, as well as what will be returned by the DSS as a result of the patient evaluation request.
349 Thus, when the need for a patient evaluation arises in a CDS system, the CDS system is able to (i)
350 obtain the required patient data from its clinical data repositories, (ii) provide the requisite data to the
351 DSS and request that the patient be evaluated using the specified knowledge modules, (iii) obtain
352 machine-interpretable decision support results regarding the patient, and (iv) parse and use the results
353 as appropriate in meeting the functional requirements of the application. **Figure 1** illustrates this
354 interaction graphically. Of note, all of the core information exchanged in the illustrated interactions

could potentially be represented using HL7 v3 content. The use of HL7 v3 content for fulfilling the semantic requirements of a DSS is discussed in greater detail in Section 2.1.4.

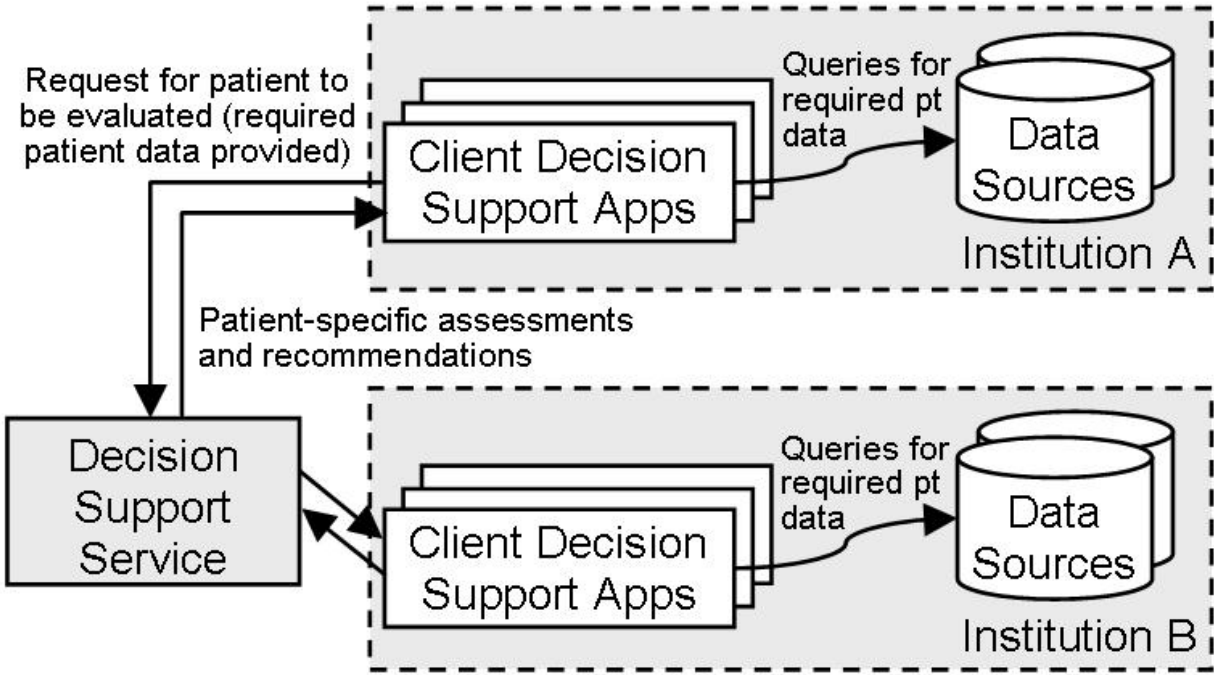


Figure 1. Schematic representation of interaction between clients and a DSS

As an optional feature, a DSS may allow the client to specify an analysis time other than the present when requesting a patient evaluation. This feature is useful, for example, when outpatient care reminder sheets need to be printed in batch during the business day prior to the actual clinic session. Furthermore, the ability to designate any time in the past or the future as the evaluation time significantly facilitates testing, as static test cases will not become obsolete with the passage of time. This ability to specify the time at which a knowledge module evaluation is to take place is similar to how a HL7 v3 RIM Act can be scheduled to occur at a desired point in time through the use of the “intent” mood and the specification of the relevant activityTime.

2.1.2.1 Notable Aspects of Interactions between System Actors

This section outlines several notable aspects regarding how a DSS, client CDS system, and data sources interact with one another to meet decision support needs.

2.1.2.1.1 No Direct Interactions between a DSS and Data Sources

As illustrated in **Figure 1**, a DSS never interacts directly with data sources. Instead, a DSS specifies the data required for evaluating a patient using a knowledge module. The client CDS system in turn retrieves the required data from relevant data sources and provides the data to the DSS when requesting a patient evaluation.

375 **2.1.2.1.2 Support for Iterative Interaction between CDS System and DSS to Identify**
376 **Additional Data Needs**

377 For a relatively simple DSS knowledge module, it would be acceptable for a CDS system to collect all
378 of the knowledge module's data requirements and to provide that data to the DSS in a single request
379 for a patient evaluation.

380 In the case of a more complex knowledge module, however, it may be desirable for a CDS system to
381 interact with a DSS in an iterative manner, in which a CDS system initially provides only a minimal
382 subset of the data required by the knowledge module for evaluating a patient. If the data provided by
383 the CDS system is not sufficient for reaching a conclusion, the DSS specifies additional data
384 requirements in an incremental manner.

385 Through this type of an iterative interaction, a CDS system can avoid collecting unnecessary data from
386 its data sources. For example, if a CDS system wishes to use a DSS knowledge module to evaluate a
387 patient's need for a Pap test, the CDS system could first provide the DSS with the patient's age and
388 gender. If the patient is a woman in the relevant age range, the DSS would notify the CDS system that
389 a further data requirement is the patient's record of Pap tests from the past three years. However, if the
390 patient is not a woman in the relevant age range, the DSS would notify the CDS system that a Pap test
391 is not applicable for the patient, and no further processing would be required on the part of the CDS
392 system.

393 For a detailed illustration of how a DSS can support such iterative interactions with a client CDS
394 system, see the business scenario described in Sections 3.2.2.2 and 7.1.2.2.

395 **2.1.3 Overall Potential Scope of the Service**

396 The primary functionality provided by a DSS is the receipt of patient data as the input and the return of
397 patient-specific conclusions as the output. A DSS also provides supplemental operations to support
398 this patient evaluation functionality (**Table 4**).

399 Of note, a DSS could be used to evaluate entities other than individual patients (e.g., patient
400 populations). For example, a DSS could be used to evaluate a group of patients to assess whether there
401 are any indications of an emerging infectious disease outbreak within that population. However, the
402 primary focus of this specification lies in the use of a DSS to evaluate individual patients. Thus, while
403 the evaluation of other entities (e.g., patient populations) is not excluded from the scope of the service,
404 the business scenarios explicitly considered in this specification (Section 3) focus on the evaluation of
405 individual patients.

406 As described earlier in Section 2.1.2, the scope of a DSS knowledge module may be narrow (e.g., an
407 infant's need for a varicella vaccination) or broad (e.g., a patient's need for any general health
408 maintenance procedures). With regard to the data required for generating the inferences, a DSS
409 knowledge module may require the provision of various types of data. These data requirements may
410 include, but are not limited to, demographic data, data on healthcare acts (e.g., procedures), and data
411 on context (e.g., whether the patient is currently being seen in an outpatient or inpatient setting, or
412 whether a specific diagnostic test can be performed at the current health care facility).

413 A DSS is permitted to return evaluation results using a variety of information constructs. Information
414 constructs that may be used for communicating decision support results may include, but are not
415 limited to, RIM acts (e.g., an HL7 medication entity with a mood code indicating that the medication
416 should be ordered), dates (e.g., the date that a test was last performed, or the date at which a test will be
417 due), and Boolean values (e.g., whether a patient is in need of a pneumococcal vaccine).

418 With regard to the types of applications intended to be supported by the specification, the DSS is
419 designed primarily to facilitate the implementation and maintenance of systems that assist patient-
420 specific decision making by clinicians (i.e., CDS systems targeted to clinicians). However, the DSS
421 could be used to support other types of applications as well. For example, the inferences obtained
422 from a DSS could be used to generate care reminder letters for patients. Also, patient evaluation
423 requests could be repeated across a patient population in order to obtain population-level statistics. For
424 example, by asking a DSS provider to evaluate each diabetic patient in a clinic with regard to the
425 patient's compliance with diabetes care guidelines, a reporting system would be able to easily calculate
426 the proportion of diabetic patients in the clinic in compliance with the recommended care metrics.
427 Finally, a DSS could be adapted so that it returns reference information relevant to the care of a patient
428 rather than an assessment or a recommendation regarding the patient. Section 3.3.2.1 provides an
429 example of how a DSS can be utilized to support this type of decision support need.

430 Of note, several aspects of the DSS are considered to be out of scope in terms of formal specification
431 and standardization. To begin, what a client does with the evaluation result provided by a DSS is
432 considered out of scope for the purposes of standardization. In addition, the mechanism used by a
433 client to obtain the data required for evaluating a patient (e.g., the use of a service such as RLUS or the
434 use of a direct database query) is also considered to be out of scope. Finally, the mechanism used by a
435 DSS to generate patient-specific evaluation results is also considered out of scope for the purposes of
436 standardization. As long as a DSS meets the functional requirements of the service, it is free to use
437 whatever knowledge representation formalism it believes is most appropriate when implementing its
438 decision support capabilities.

439 **2.1.4 Use of HL7 Version 3 Content**

440 As noted earlier in Section 1.1.3, HSSP SFMs are not limited to the use of HL7 content as service
441 payloads. However, each SFM must support the use of HL7 content to fulfill the semantic
442 requirements of the service, and it is expected that future HL7 ballots will formalize DSS semantic
443 profiles that require the use of relevant HL7 v3 domain content (see Sections 2.3.6 and 6).

444 While new HL7 v3 content may need to be created to meet the needs of DSS implementations (see
445 Section 2.3.6), existing HL7 v3 content could be used to fulfill many of the needs of a DSS
446 implementation. In particular, HL7 v3 information models could be used (1) to specify the semantics
447 by which data should be provided to the DSS for evaluating patients using a knowledge module; (2) to
448 specify the semantics by which the query conditions for knowledge module data requirements are
449 expressed by the DSS; and (3) to specify the semantics by which patient evaluation results will be
450 returned by the DSS (see Sections 2.3.3.2 and 2.3.3.4). Also, HL7 v3 information models and data
451 types could be used to specify knowledge module meta-data and knowledge module search criteria
452 (see Figure 4 in Section 2.3.4 and Section 2.3.4.3.2). Thus, HL7 v3 artifacts could be used to meet a
453 DSS client's supplemental information needs (see Table 4 in Section 2.1.2). Furthermore, the medical
454 knowledge captured in some HL7 v3 artifacts (e.g., HL7 Patient Care TC's Guideline construct) could
455 potentially be used to fulfill the functional requirements of a knowledge module (see Section 2.1.4.2).

456 As will be noted in Section 2.3.3.4, HL7 v3 content from various domains could be used to meet the
457 semantic requirements of a DSS. For example, information models from the Patient Care TC, the
458 Structured Documents TC, and the Clinical Decision Support TC could all be used by a DSS. In
459 particular, the Clinical Decision Support TC and the Patient Care TC have or are expected to have a
460 number of information constructs supportive of DSS implementations. Thus, the potential use of HL7
461 v3 content from these two domains is explicitly considered next.

462 2.1.4.1 Potential Use of Clinical Decision Support TC's Domain Content

463 Currently, the HL7 v3 Clinical Decision Support domain contains a proposed standard for order set
464 representation and a proposed standard for the retrieval of context-sensitive reference information.
465 The latter standard is also referred to as the Infobutton standard.

466 With regard to the order set standard, a DSS knowledge module could potentially take patient data
467 such as age, gender, co-morbidities, and chief complaint as the input and provide recommended order
468 set(s) in the standard HL7 format as the output. Furthermore, with regard to the Infobutton standard,
469 the capabilities of the Decision Support System and Information Resource application roles could be
470 exposed through a DSS interface. See the business scenario in Sections 3.3.2.1 and 7.2.2.1 for a
471 detailed exploration of how the semantic content defined in the Infobutton standard could be used by a
472 DSS.

473 Also, as noted in Section 2.3.6, it is anticipated that HL7 v3 information constructs (e.g., RMIMs) may
474 be developed and balloted in the future if they would be useful as standardized DSS service payloads.
475 The Clinical Decision Support domain is expected to serve as the home for many of these new
476 information constructs.

477 2.1.4.2 Potential Use of Patient Care TC's Domain Content

478 Within the HL7 v3 Patient Care domain, various artifacts have been described that support the
479 semantic needs of a DSS. For example, the Patient Care TC's Care Statement information model or a
480 similar model could potentially be used to specify the semantics by which data should be provided to
481 the DSS for evaluating patients using a knowledge module. Also, the Patient Care TC's Care Record
482 Query RMIM or a similar model could potentially be used to specify the semantics by which the query
483 conditions for knowledge module data requirements are expressed by the DSS. Furthermore, the
484 Patient Care TC's Care Plan RMIM could potentially be used to specify the semantics by which patient
485 evaluation results will be returned by a DSS. Moreover, medical knowledge captured using the Patient
486 Care TC's Guideline construct could potentially be used to specify necessary patient data and to
487 generate a patient-specific care plan that includes a rationale of why particular parts of the guideline
488 were not carried forward to the care plan.

489 490 **2.2 The Reason Why the Service Specification is Needed**

491 ***2.2.1 Explanation of Why the Service is Needed***

492 As discussed in section 2.1.1, the rationale for creating the DSS specification is as follows: (i) there is
493 a great need to improve the quality and safety of health care; (ii) CDS systems represent one of the
494 most promising strategies for improving care quality, but their use is limited; (iii) one important reason
495 for this limited utilization is the difficulty and cost associated with implementing effective CDS
496 systems; (iv) the widespread adoption of the DSS standard should reduce the cost of implementing and
497 maintaining a CDS system, thereby increasing the utilization of CDS systems in clinical care; and (v)
498 increased utilization of CDS systems should help to improve care quality and to ensure patient safety.

499 ***2.2.2 Explanation of Why a Standard is Needed for the Service***

500 Without a commonly agreed upon standard for the DSS, service clients would need to implement
501 different interfaces when dealing with different DSSs or when switching DSSs. Similarly, the lack of a
502 standard would result in service providers reaching only a small fraction of potential clients, as clients

503 would need to invest in provider-specific interfaces before being able to make use of the functionality
504 offered by a DSS.

505 A commonly accepted standard for the DSS would make it more attractive for service clients to invest
506 in the infrastructure required for using the DSS to meet its decision support needs, as they would be
507 able to use the same interface to interact with multiple service vendors. From the vendor's perspective
508 as well, a standard for the DSS is needed to increase the pool of potential customers and to reduce the
509 risk involved with investing in the service framework.

510 ***2.2.3 Vendor Viewpoint and Potential Business Opportunity or Niche***

511 From the perspective of a vendor, the acceptance of the DSS as an HL7 standard would provide several
512 important benefits. First, a DSS standard should lead to a significant expansion of their potential client
513 base. This expansion should occur due to the fact that clients should be more inclined to invest in the
514 interface required for interacting with a vendor, as the interface would no longer be vendor-specific
515 and would be re-usable for accessing knowledge from other DSS providers. Given this expansion of
516 the client base, and given the highly scalable nature of the service framework, a DSS provider that
517 achieves economies of scale would be able to increase its revenues and earnings, maintain a high
518 quality of service, and lower the price that it charges on a per-client basis.

519 Also, because the DSS can be implemented as a service wrapper around existing capabilities, a DSS
520 provider that has an established client base would be able to continue providing knowledge services
521 using existing approaches as well (e.g., via existing application programming interfaces).
522 Furthermore, because the DSS does not dictate how knowledge should be represented, the DSS
523 provider can continue to encode medical knowledge using the approach that it deems to be most
524 appropriate for its purposes.

525 Finally, a vendor with a superior DSS implementation would be able to license its implementation of
526 the framework to other knowledge vendors or to other entities interested in sharing its patient
527 evaluation capabilities via a DSS. Non-vendor entities that may wish to become DSS providers
528 include federal or state organizations with an interest in finding more effective ways of getting their
529 recommendations implemented in practice, such as Medicare, Medicaid, and the Agency for
530 Healthcare Research and Quality in the United States. Also, health systems may be interested in
531 supplementing the knowledge available from commercial DSS providers by acting as a DSS provider
532 itself.

533 ***2.2.4 Consumer Viewpoint and the Value Offered by the Work Product***

534 DSS consumers would potentially include any entity that wishes to facilitate the implementation and
535 maintenance of decision support systems. These service consumers may include EHR, CPOE, e-
536 Prescribing, and hospital information system (HIS) vendors, as well as healthcare institutions and their
537 clinical departments.

538 From the viewpoint of these DSS customers, the primary value offered by the work product is the
539 ability to leverage the decision support capabilities of multiple DSSs through a common service
540 interface. By leveraging the capabilities of the DSS, the service customer should be able to reduce the
541 cost and difficulty associated with developing and maintaining decision support applications.

542 Another advantage of the DSS framework is that it is highly secure. The DSS client rather than the
543 DSS retrieves all patient data (see Section 2.1.2.1.1), and there is usually no need for a DSS to know
544 who is being evaluated. Consequently, patient identifiers are generally not sent to a DSS. Also, the
545 DSS does not need to be authorized to access the client's data repositories. As a result, a high level of
546 security is attained by the fact that the client controls all read/write calls to its clinical repositories.

547 A final advantage to the DSS framework is that it significantly facilitates CDS system maintenance, as
548 the medical decision logic used to reach patient evaluations are encapsulated in discrete knowledge
549 modules that are tagged with meta-data, version-controlled, and maintained centrally on behalf of
550 multiple clients.

551

552 **2.3 Structure of the Service**

553 **2.3.1 Interfaces**

554 This specification aims to standardize the functionality of three identified interfaces: Meta-data
555 Discovery, Query, and Evaluation. These interfaces are described in detail in Section 5 and are
556 summarized below.

- 557 • The **Meta-data Discovery** interface provides operations for discovering and examining meta-data
558 associated with a DSS or its knowledge modules, such as profiles, knowledge module
559 requirements, knowledge module traits, and semantic signifiers.
- 560 • The **Query** interface provides operations for discovering and examining knowledge modules of
561 interest. Included in this interface are operations for identifying the data required for evaluating a
562 patient using a knowledge module.
- 563 • The **Evaluation** interface provides operations for obtaining evaluation results using specified
564 knowledge modules.

565 The above interfaces are used by DSS clients to find and utilize DSS knowledge modules to meet
566 decision support needs. In addition to these core service interfaces, it is anticipated that individual
567 DSS implementations may provide management interfaces that can be used by a DSS provider to
568 manage and maintain knowledge modules and their associated meta-data. Such management
569 interfaces are not specified in this functional model, however, as (1) a DSS provider may elect to
570 manage and maintain knowledge modules and their associated meta-data without the use of such
571 interfaces, and as (2) the availability and standardization of such management interfaces for use by
572 DSS providers is not required to allow for interoperable use of DSSs by service clients. However, this
573 SFM does recommend that the OMG requires technical RFP submitters to further consider and
574 comment on the utility of specifying standard interfaces for performing such management operations
575 (see Section 10).

576 **2.3.2 Profiles**

577 This specification is designed as a generic service framework which can be adapted in various ways to
578 meet clients' clinical decision support needs. While this flexibility is desirable, too much flexibility
579 could make it more difficult to implement a DSS and/or to achieve plug-and-play interoperability
580 among multiple DSSs.

581 This and other HSSP SFMs utilize **service profiles** in order to constrain this flexibility and to facilitate
582 interoperability and implementation. Service profiles, also referred to as profiles, are named
583 constraints placed on a service. There are three types of service profiles, as defined below:

- 584 • A **functional profile** specifies a set of service operations that must be supported by a service
585 claiming conformance to that profile
- 586 • A **semantic profile** specifies constraints on the information constructs that serve as payloads
587 within service operations.

- 588 • A **conformance profile** consists of one or more functional profiles, one or more semantic profiles,
589 and zero or more other constraints to be placed on a service.

590 Of note, it is envisaged that many profiles will be defined after the adoption of this SFM. Some of
591 these profiles may be specified as formal, balloted profiles defined by standards development
592 organizations such as HL7 and OMG, while other profiles may be specified as informal profiles
593 defined by individual vendors, institutions, or other organizations.

594 **2.3.3 Semantic Signifiers**

595 This specification makes extensive use of “semantic signifiers,” which have been defined by the HSSP
596 to facilitate the use of diverse semantic content within generic service interfaces. This section
597 describes semantic signifiers in depth and delineates their use within this specification.

598 **2.3.3.1 Description**

599 The HSSP defines semantic signifiers as identifiers of information constructs that specify the structure
600 and meaning of data. Semantic signifiers may identify standardized information constructs from HL7
601 (e.g., an HL7 v3 RIM, CMET, or template), standardized information constructs from a standards
602 development organization other than HL7 (e.g., a DICOM image format), or non-standard local
603 information constructs (e.g., Health System A’s laboratory data exchange format).

604 Several existing and emerging standards are closely aligned with HSSP semantic signifiers. The HL7
605 Templates Special Interest Group (SIG) is presently in the process of harmonizing requirements from
606 among the CEN, OpenEHR, and HL7 communities. Also, the Dutch National IT Institute for
607 Healthcare is developing “Care Information Models”^{7,8}; examples of these models can be found at
608 www.zorginformatiemodel.nl. Each of these communities is using one or more formalisms to specify
609 what HSSP semantic signifiers are intended to specify, which is the structure and semantics of
610 information.

611 Part of the rationale for coining the new term was to circumvent potential misconceptions or
612 misalignments with these existing work products, as they have not been rigorously assessed relative to
613 the HSSP work. The expectation is that constructs such as those from the HL7 Templates SIG,
614 OpenEHR, and CEN would be usable within HSSP implementations and subsequent technical
615 specifications as semantic signifiers. Where the semantic signifier refers to HL7 RIM semantics, a
616 RIM-derived HL7 model is expected to be used to express the RIM semantics.

617 **2.3.3.2 Usage within DSS**

618 In this specification, semantic signifiers are used for the following purposes: (1) to specify the
619 semantics by which data should be provided to the DSS for evaluating patients using a knowledge
620 module; (2) to specify the semantics by which the query conditions for knowledge module data
621 requirements are expressed by the DSS; and (3) to specify the semantics by which patient evaluation
622 results will be returned by the DSS.

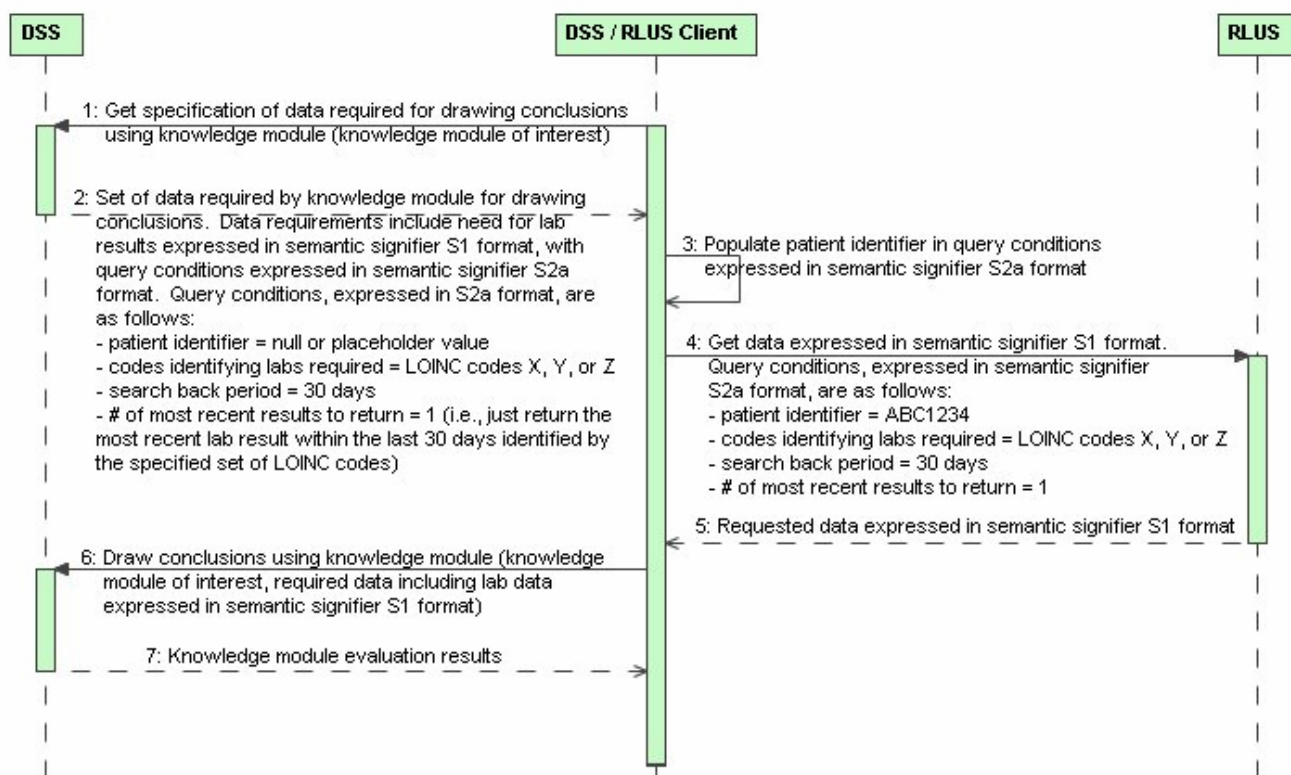
⁷ Goossen, WTF (2006). Intelligent semantic interoperability: integrating knowledge, terminology and information models to support stroke care. In: Park HA, Murray P, Delaney C (Eds). Consumer-Centered Computer-Supported Care for Healthy People. Proceedings of NI2006. Amsterdam etc. IOS Press. Pp. 435-439. Studies in Health Technology and Informatics, volume 122.

⁸ van der Kooij J, Goossen WTF, Anneke TM. Goossen-Baremans, Plaisier N. Evaluation of Documents that Integrate Knowledge, Terminology and Information Models. In: Park HA, Murray P, Delaney C (Eds). Consumer-Centered Computer-Supported Care for Healthy People. Proceedings of NI2006. Amsterdam etc. IOS Press. Pp. 519-522. Studies in Health Technology and Informatics, volume 122.

623 2.3.3.3 Relationship to RLUS Semantic Signifiers

624 The first two ways in which the DSS uses semantic signifiers correlate with the ways in which
 625 semantic signifiers are used by the HSSP Retrieve, Locate, and Update Service (RLUS). Specifically,
 626 if a DSS specifies that it requires patient data that (a) are represented in semantic signifier S1 format
 627 and (b) fulfill query conditions expressed in semantic signifier S2 format, the required data could be
 628 obtained by querying a RLUS for data that (a) are represented in semantic signifier S1 format and (b)
 629 fulfill query conditions represented in semantic signifier S2 format or in a different semantic signifier
 630 format closely related to the S2 format. A DSS and RLUS may require query conditions to be
 631 represented using slightly different semantics, as a DSS will generally specify time-oriented query
 632 parameters in relative terms (e.g., obtain the most recent serum potassium level for the patient from the
 633 past 30 days), whereas a RLUS may require time-oriented query parameters to be specified in absolute
 634 terms (e.g., obtain the most recent serum potassium level for the patient from 2006-05-01 to 2006-06-
 635 01). Also, whereas a DSS will not specify an actual patient identifier as a query parameter, a RLUS
 636 would generally require a patient identifier as a core query parameter.

637 **Figure 2** provides an example in which the same semantic signifier is used by a DSS and a RLUS to
 638 express query parameters, and **Figure 3** provides an example in which the RLUS query conditions are
 639 expressed using semantics that can be derived from, but are not identical to, the semantics used by the
 640 DSS to express query conditions.



641
 642 **Figure 2.** Example use of semantic signifiers by a DSS and a RLUS, in which both services utilize the same
 643 semantic signifiers to express the data query model.

644

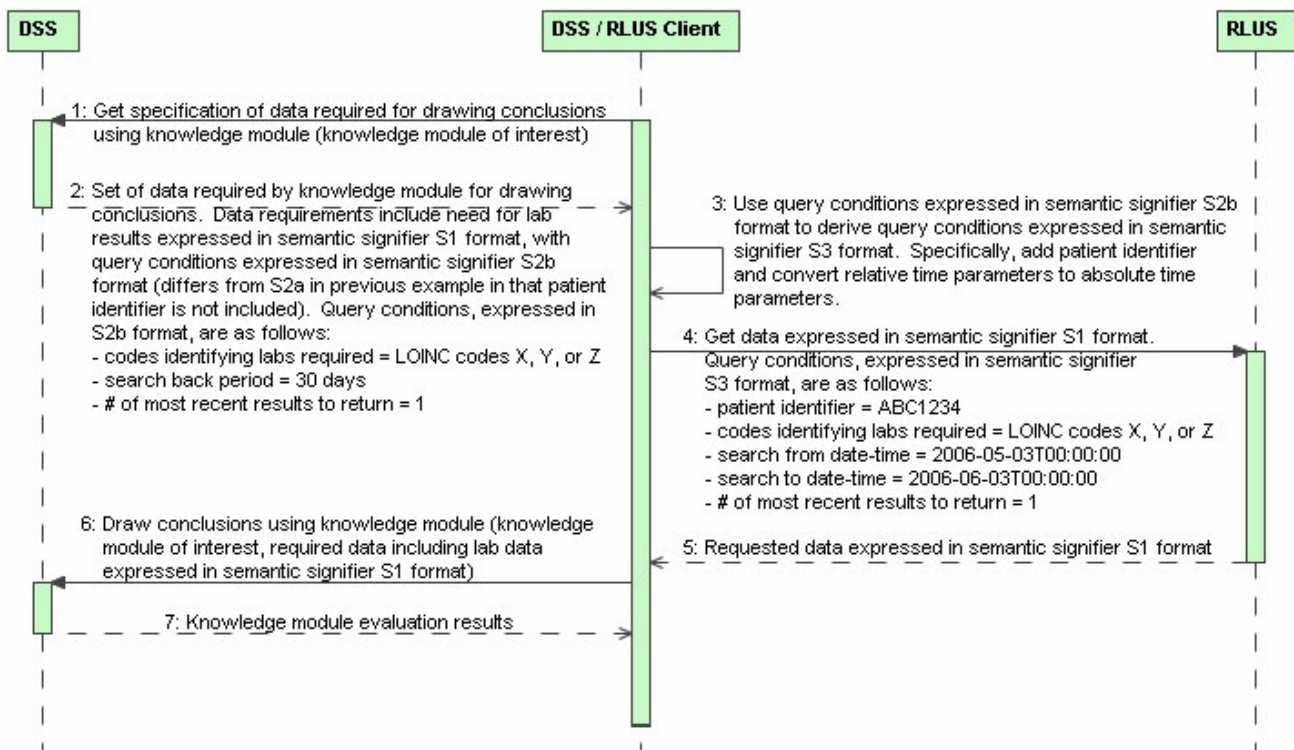


Figure 3. Example use of semantic signifiers by a DSS and a RLUS, in which RLUS data query parameters are derived from DSS data query parameters.

2.3.3.4 Semantic Signifier Examples

Examples of semantic signifiers, and their corresponding usage by a DSS, are provided in **Table 5** below.

Table 5. Semantic signifier examples.

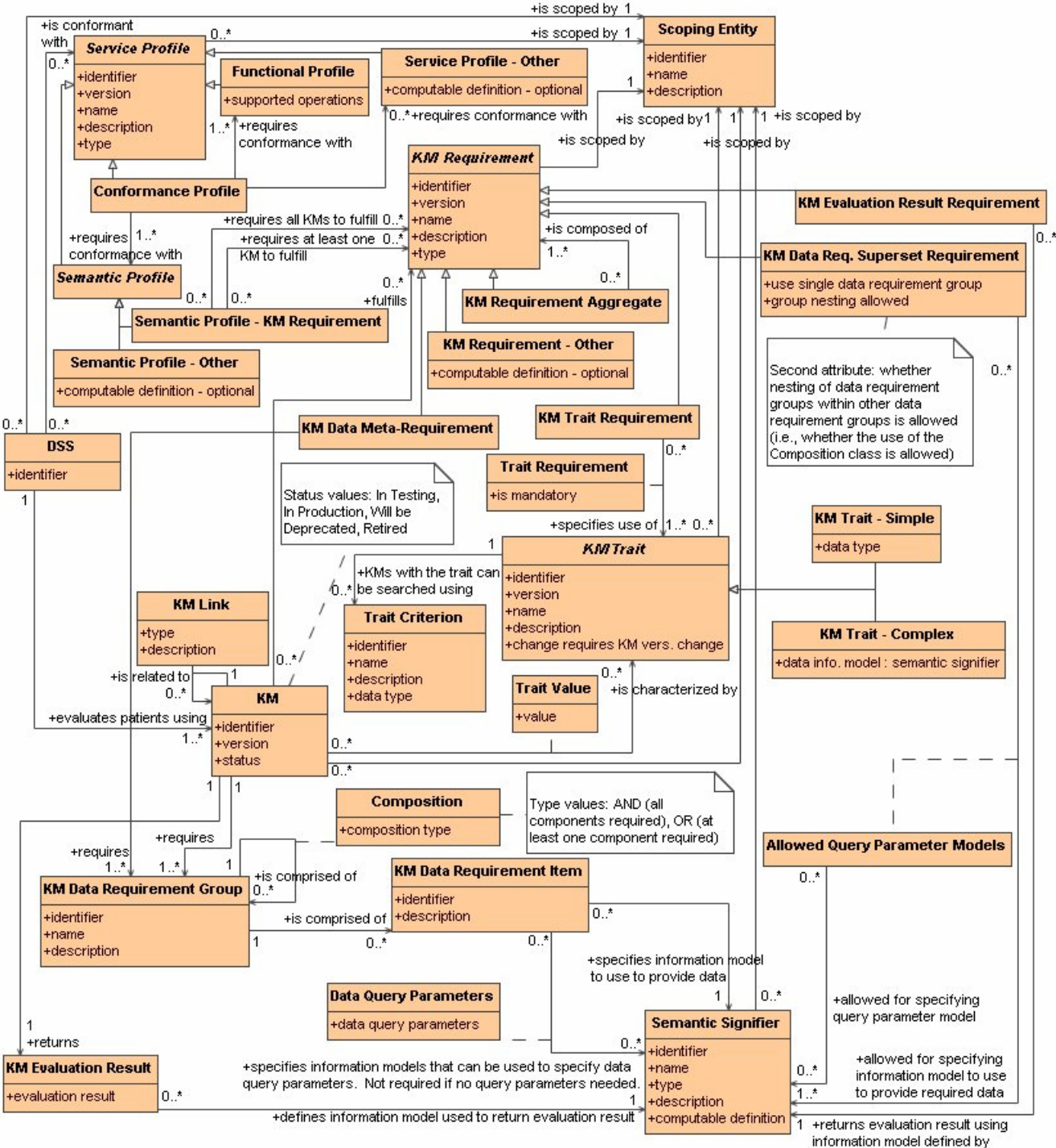
Type	Semantic Signifier Example	Used to Specify How Required Data Should Be Returned	Used to Specify Query Parameters	Used to Specify How Patient Evaluation Results Will Be Returned
HL7 RMIM	Patient Care TC's Care Record RMIM	X		
	Structured Documents TC's CDA Release 2 RMIM	X		
	Variant of Patient Care TC's Care Record Query RMIM in which query time period is expressed in relative terms (e.g., as "care record from past year" rather than as "care record from 2005-06-03 to 2006-06-03")		X	
	Variant of Medical Records Parameter Query Model RMIM in which query time period is expressed in relative terms		X	

Type	Semantic Signifier Example	Used to Specify How Required Data Should Be Returned	Used to Specify Query Parameters	Used to Specify How Patient Evaluation Results Will Be Returned
	DSS evaluation result RMIMs to be defined within Clinical Decision Support TC			X
HL7 Template	<p>A Blood Pressure <i>template</i> that specifies an Observation act containing the following data elements:</p> <ul style="list-style-type: none"> - systolic value - diastolic value - cuff size - cuff position - laterality - patient position <p>In the above example, each of these elements can be represented by codified terms from some specific enumerated terminology or numeric value ranges, and the template would also define the information structure to be used.</p>	X		
Semantic signifiers from non-HL7 standards development organizations	OpenEHR archetype for blood pressure	X		
	ASTM International's Continuity of Care Record	X		
	DICOM image specifications	X		
Non-standardized, local semantic signifiers	A Regional Health Information Organization's specification of how problem lists are to be represented and shared, including a specification of the terminologies used.	X		
	Knowledge vendor A's DSS evaluation result semantics expressed using the HL7 RMIM formalism			X

654 **2.3.4 Underlying Computational Meta-Model**

655 **Figure 4** provides the computational meta-model that underlies the DSS and its service interfaces.
656 Core aspects of this model are described below.

657



658 **Figure 4.** Computational meta-model for DSS. KM = DSS knowledge module.
659

660 2.3.4.1 Scoping Entity

661 Many classes within the computational model are scoped by a scoping entity. Example scoping
662 entities include standards development organizations (e.g., HL7), a geographic location (e.g., a nation),
663 and vendors (e.g., a single knowledge vendor or an association of cooperating knowledge vendors).

664 2.3.4.2 DSS

665 A DSS evaluates patients using one or more knowledge modules. A DSS can be conformant with one
666 or more functional profiles that define the service operations supported by the DSS. To promote
667 interoperability, it is anticipated that only a small number of functional profiles will be defined, and
668 that all functional profiles will support a set of operations defined as being minimally required by all
669 functional profiles (see discussion of profiles in Section 6). In addition, a DSS can be conformant with
670 one or more semantic profiles that restrict or otherwise specify the semantic content supported by the
671 DSS. A semantic profile can be expressed in terms of the knowledge module requirements that are
672 fulfilled by some or all of a DSS's knowledge modules. A DSS can also be conformant with one or
673 more conformance profiles, which consist of one or more functional profiles, one or more semantic
674 profiles, and zero or more other constraints.

675 2.3.4.3 DSS Knowledge Module

676 A DSS knowledge module is defined by an identifier and a version. A knowledge module also is
677 characterized by a status, consisting of "in testing," "in production," "will be deprecated," and
678 "retired." The version of the knowledge module shall change if the data requirement specification or
679 evaluation result specification changes, or if certain knowledge module traits are changed (See Section
680 2.3.4.3.2 below).

681 A knowledge module can also have relationships with other knowledge modules. For example, a
682 knowledge module can be an updated version of an existing module, or it may be a closely related
683 variant that differs from another knowledge module only in terms of the vocabularies that it uses to
684 specify data requirements. Regardless of the relationships between knowledge modules, each
685 knowledge module must be able to stand on its own in meeting the needs of DSS clients. In other
686 words, each knowledge module must be encapsulated and exposed in such a way that a DSS client can
687 obtain all the information required for utilizing that knowledge module without having to consult one
688 or more additional knowledge modules. Moreover, it is up to the DSS whether it chooses to expose
689 internal relationships between knowledge modules (e.g., the fact that a given knowledge module makes
690 use of one or more "nested" knowledge modules to reach a conclusion). Further specification of
691 allowed knowledge module relationships is expected to occur at the level of the OMG technical
692 specification (see Section 10.5.2).

693 **2.3.4.3.1 Knowledge Module Requirements**

694 A knowledge module can fulfill one or more knowledge module requirements. Example types of
695 knowledge module requirements include: (1) requirements that specify the traits that must or can be
696 associated with a knowledge module (see Section 2.3.4.3.2 below); requirements that constrain or
697 otherwise specify the set of data that can be required by a knowledge module (see Sections 2.3.4.3.3
698 and 2.3.4.3.4 below); and requirements that specify how evaluation results will be returned (see
699 Section 2.3.4.3.5 below). Note that a DSS semantic profile can be specified in terms of the knowledge
700 module requirements that are fulfilled by some or all of a DSS's knowledge modules.

701 **2.3.4.3.2 Knowledge Module Traits**

702 A knowledge module can be described by one or more traits. These traits can be used to search for
703 knowledge modules or to describe a given knowledge module. Example traits include the last review
704 date, steward organization, and keywords. A knowledge module requirement may specify that a
705 change to a specified knowledge module must result in a change in the knowledge module version
706 number.

707 **2.3.4.3.3 Knowledge Module Data Requirement Groups**

708 A knowledge module is associated with one or more data requirement groups. If a knowledge module
709 contains more than one data requirement group, the data required by each group must be provided by
710 the service client in order for a patient to be properly evaluated using the knowledge module.

711 A data requirement group can be comprised of other data requirement groups. The parent data
712 requirement group can require that clients fulfill the data requirements specified by each of the
713 contained requirement groups. Alternatively, the parent data requirement group may specify that the
714 client simply needs to fulfill the data requirements specified by at least one of the contained data
715 requirement groups.

716 **2.3.4.3.4 Knowledge Module Data Requirement Items**

717 A knowledge module data requirement group can contain one or more knowledge module data
718 requirement items. Each data requirement item contains a semantic signifier that specifies the
719 information model that a client should use to provide the required data and zero or more semantic
720 signifiers that specify how query parameters may be expressed. Each semantic signifier specifying the
721 query information model is accompanied by the contents of the query parameters. Query parameter
722 models and query parameter contents do not need to be specified in the case where specifying the data
723 information model is considered sufficient for specifying the data required (e.g., when specifying that
724 the contents of a patient's problem list is desired, rather than when specifying that the contents of a
725 patient's problem list is desired if the problem is asthma or diabetes mellitus).

726 As noted in the Relationship to RLUS Semantic Signifiers section above (Section 2.3.3.3) and in the
727 Implementation Considerations section below (Section 2.4), data requirement items are designed to
728 allow for straightforward translation into a RLUS data query.

729 **2.3.4.3.5 Knowledge Module Evaluation Result**

730 Once provided with the data required by a knowledge module, a DSS uses the knowledge module to
731 generate evaluation results. The knowledge module uses a semantic signifier to define the information
732 model used to return the evaluation results.

733 **2.3.5 Service Aspects Defined in this Specification**

734 This Service Functional Model (SFM) defines the following aspects of a DSS:

- 735 - The functional capabilities of a DSS
- 736 - The service interfaces of a DSS
- 737 - The computational model underlying DSS interfaces
- 738 - Two functional profiles for DSSs – the Core DSS Functional Profile and the Advanced Time
739 Handling DSS Functional Profile
- 740 - A knowledge module requirement definition that specifies the minimum set of meta-data that is
741 to be associated with all DSS knowledge modules

- A semantic profile that mandates support for this knowledge module meta-data requirement by a conformant service
- A framework for defining semantic profiles that constrain the information constructs allowed in service requests and/or responses

2.3.6 Service Aspects to be Defined in Future Specifications

This SFM purposely leaves several aspects of the DSS to be defined in future specifications. These anticipated future specifications are described below.

Based on the HL7 DSS SFM, a Request for Proposal (RFP) will be formulated by the Object Management Group (OMG) Healthcare Domain Task Force. Recommendations for this OMG RFP process are specified in Section 10. The OMG RFP will request that vendors develop a technical specification for the DSS that fulfills the functional requirements specified by the HL7 SFM. Following balloting and approval, this technical specification for the DSS will be available as an OMG specification. It is anticipated that this OMG specification will include both a platform-neutral, UML DSS service interface specification as well as one or more platform-specific DSS service interface specifications, including a SOAP Web service specification.

Furthermore, it is anticipated that one or more semantic profiles for the DSS will be developed and balloted within HL7 as the need arises. In most cases, the specification of a semantic profile is expected to be preceded by the specification of one or more knowledge module requirements (see Section 2.3.4.3.1). For example, a Core Data Requirement Knowledge Module Requirement might be defined that specifies a superset of the types of data that can be required by a DSS knowledge module claiming conformance to the requirement. Then, a semantic profile can be defined that requires conformant services to support one or more knowledge modules that fulfill this named requirement. Of note, both semantic profile specifications and knowledge module requirement specifications are expected to be balloted as normative HL7 specifications.

In essence, these semantic profile specifications and knowledge module requirement specifications are intended to allow groups of interested parties to specify constraints on the generic DSS specification to facilitate interoperability. The framework for specifying these profiles and knowledge module requirements is described in Section 6.

Finally, it is anticipated that HL7 v3 information constructs (e.g., RMIMs) may be developed and balloted in the future if they would be useful as standardized DSS service payloads but have not yet been specified. For example, it may be appropriate to develop and standardize information constructs representing DSS evaluation results within the HL7 Clinical Decision Support Technical Committee. These information constructs would be referenced using semantic signifiers.

2.4 Implementation Considerations

2.4.1 Flexibility for Service Providers

As discussed in Section 2.1.3, the mechanism used by a DSS to generate evaluation results is considered out of scope for the purposes of standardization. As long as a DSS meets the functional requirements of the service, it is free to use whatever knowledge representation formalism it believes is most appropriate when implementing its decision support capabilities.

2.4.2 Flexibility for Service Clients

From the perspective of the service client, the DSS offers substantial flexibility in terms of how the various service operations can be orchestrated in order to meet functional needs. For example,

784 knowledge module data requirements can be discovered at design time or at run time; required data can
785 be obtained via a RLUS or via a direct database connection; and a DSS can be leveraged in batch mode
786 (e.g., to generate patient reminder letters) or in an interactive mode. The business scenarios described
787 in Sections 3 and 7 provide examples of how a DSS can be used in various ways to meet the needs of a
788 decision support application.

789 **2.4.3 Ability to Use a RLUS to Fulfill DSS Data Requirements**

790 The DSS specification allows knowledge module data requirements to be fulfilled using a RLUS. The
791 business scenarios described in Sections 3 and 7 provide illustrations of this capability.

792 **2.4.4 Interactive Use of a DSS**

793 It is possible to use a DSS in an interactive manner, in which a client system makes iterative calls to
794 one or more knowledge modules to fulfill a decision support need. The business scenarios described in
795 Sections 3 and 7 provide illustrations of such interactive use of a DSS.

796

797 **3 Business Scenarios (Informative Content)**

798 This section describes the various business scenarios that were explicitly considered as a part of the
799 SFM specification process. A more detailed analysis of these scenarios is available in Section 7.

800 **3.1 Primary Actors**

- 801 • DSS A, DSS B, DSS C, DSS D – decision support services offered by Vendors A, B, C, and
802 D, respectively
- 803 • DSS query system – a system that can be used to query a DSS for information
- 804 • Engineer Ed – a software engineer implementing CDS capabilities for a DSS client using
805 DSS A, B, C, and/or D
- 806 • CDS system – a clinical decision support system that uses a DSS to provide clinical decision
807 support capabilities to end-users
- 808 • RLUS – Retrieve, Locate, and Update Service
- 809 • EHR system – electronic health record system
- 810 • CPOE system – computerized provider order entry system
- 811 • e-Prescribing system – electronic prescribing system
- 812 • Insurance Company IC – a health insurance company
- 813 • Doctor David – a clinician. David plays various clinical roles in the following scenarios and
814 is re-defined at the beginning of each scenario.
- 815 • Jane Doe, John Smith – patients. Jane and John have different characteristics in the
816 following scenarios and are re-defined at the beginning of each scenario.
- 817

818 **3.2 Primary Scenarios**

819 **3.2.1 Generic Primary Scenarios**

820 This section outlines scenarios that cover the generic steps involved in making use of a DSS to meet
821 decision support needs.

822 **3.2.1.1 Identification of DSS Capabilities**

823 Engineer Ed uses a DSS query system to identify the profile(s) supported by DSS A.

824 **3.2.1.2 Identification of Knowledge Modules of Interest**

825 Engineer Ed uses the DSS query system to identify knowledge modules that can be used to meet his
826 CDS implementation needs. To identify knowledge modules of interest, Ed can ask DSS A questions
827 such as: (1) what knowledge module requirements are supported by DSS A's knowledge modules? (2)
828 what traits are available for searching for knowledge modules? (3) which knowledge modules possess
829 the specified knowledge requirement(s), status(es), and/or knowledge module trait(s)? (4) what
830 semantic signifiers are used by the DSS's knowledge modules to return evaluation results? (5) which
831 knowledge modules return evaluation results using the specified semantic signifier(s)? (6) what
832 semantic signifiers are used by the DSS's knowledge modules to specify their data requirements and
833 the query parameters associated with those data requirements? and (7) which knowledge modules can
834 be properly used given the data available to the client, as expressed by the semantic signifiers that
835 specify the information models that can be used to provide data and the associated semantic signifiers
836 that specify the information models that can be used to query for that data?

837 **3.2.1.3 Retrieval of Knowledge Module Traits**

838 Engineer Ed uses the DSS query system to retrieve and review the traits associated with one or more
839 knowledge modules of interest.

840 **3.2.1.4 Retrieval of Knowledge Module Data Requirements**

841 Engineer Ed uses the DSS query system to retrieve and review the data required by the knowledge
842 modules of interest to evaluate patients. In making the request for the data requirements, Engineer Ed
843 has the option of requesting all data requirements associated with the knowledge modules of interest,
844 or requesting only those data requirements that the DSS client is able to fulfill. If choosing the latter
845 option, Engineer Ed must specify as part of the request the data available to the client, as expressed by
846 the semantic signifiers that specify the information models that the client can use to provide data and
847 the associated semantic signifiers that specify the information models that the client can use to query
848 for that data. In responding to this request, the DSS also specifies whether the data available to the
849 client is sufficient for meeting the data requirements of the knowledge modules specified.

850 **3.2.1.5 Retrieval of How Evaluation Results Will be Returned**

851 Engineer Ed uses the DSS query system to retrieve and review how evaluation results will be returned
852 when a knowledge module is used to evaluate a patient.

3.2.1.6 Evaluation of a Patient Using DSS Knowledge Modules and Use of Evaluation Results to Provide Context-Appropriate Clinical Decision Support

When the need for a patient evaluation arises, a CDS system (i) obtains the required patient data from patient data source(s) (e.g., a RLUS), (ii) provides the requisite data to the DSS and requests that the patient be evaluated using the specified knowledge modules, (iii) obtains machine-interpretable decision support results regarding the patient, and (iv) parses and uses the evaluation results as appropriate in meeting the functional requirements of the application.

3.2.2 Specific Primary Scenarios

This section outlines specific scenarios that cover the use of a DSS by clients to meet their clinical decision support needs. Note the following regarding these scenarios:

- These business scenarios are **non-normative**. Specifically, profiles, semantic signifiers, knowledge modules, etc. discussed in these scenarios are meant to illustrate how a DSS *could* be instantiated and utilized rather than how a DSS *should* or *must* be used. Also, many of the business scenarios represent only one of several alternate ways in which a given decision support need could be fulfilled using a DSS. For example, a RLUS is used in many of the business scenarios below, but the use of other data retrieval mechanisms (e.g., direct database connections) would be equally valid.
- To facilitate understanding of the business scenarios, the knowledge modules and DSSs referenced in this section are documented in detail in Section 14 (**Appendix II**). These example DSSs and knowledge modules are meant to illustrate how DSSs could be instantiated to meet client needs.
- Focus is placed on the use of DSSs by CDS systems (i.e., generic business scenario 3.2.1.6), rather than on preparatory work involving the discovery of relevant knowledge modules and the configuration of a CDS system to make use of knowledge modules to meet decision support needs (i.e., generic business scenarios 3.2.1.1, 3.2.1.2, 3.2.1.3, 3.2.1.4, and 3.2.1.5).
- Due to the diversity of specific scenarios in which a DSS could be used, it is difficult to prioritize one scenario over another, or to enumerate each potential scenario. Thus, the following scenarios illustrate only a small subset of the many potential ways in which a DSS could be used.
- This section provides overviews of the business scenarios from the perspective of the end-user. Details of the business scenarios, including sequence diagrams outlining the interactions among scenario actors, are provided in Section 7.

3.2.2.1 Provision of Chronic Disease Management and Preventive Care Recommendations to a Primary Care Clinician through an EHR System

Context: Jane Doe is a 70 year old Caucasian female with diabetes mellitus. Doctor David is an internist and Jane's primary care clinician. David's practice utilizes an EHR system which uses DSSs to provide decision support capabilities.

Scenario Overview from End-User's Perspective: Jane checks into David's clinic. When David opens the patient's record in the EHR system, he is presented with a patient summary screen that contains care recommendations organized by disease or preventive care focus. These care recommendations are generated using knowledge modules hosted by DSS A.

894 Each care recommendation is accompanied by relevant patient data leading to the recommendation, a
895 link to further information on the clinical guideline applied, and a link allowing recommended orders
896 to be placed via the associated CPOE system. A screenshot from the care recommendation section of
897 Jane's patient summary screen is provided in **Appendix III, Figure 5**. David reviews Jane's care
898 needs during the encounter and places several of the orders recommended by the EHR system.

899 3.2.2.2 Provision of Medication Safety and Prescription Prior Authorization Decision 900 Support to an Oncologist through an e-Prescribing System

901 **Context:** John Smith is a 67 year old Caucasian male with hypertension and lung cancer. Doctor
902 David is an oncologist treating John's lung cancer. David's practice utilizes an e-Prescribing system
903 which uses DSSs to provide decision support capabilities.

904 **Scenario Overview from End-User's Perspective:** John is seen by David at an oncology clinic.
905 Towards the end of the visit, David begins to write prescriptions for John using an e-Prescribing
906 system.

907 When David enters a prescription, the e-Prescribing system uses DSS A to look for medication safety
908 issues such as drug-allergy contraindications, drug-drug interactions, and inappropriate dosing. David
909 is notified of any such potential problems related to the proposed prescription.

910 Furthermore, the e-Prescribing system has the proposed prescription evaluated by DSS B, which serves
911 as the national repository of medication prior authorization rules. Medication prior authorization rules
912 are rules utilized by individual insurers to determine whether a patient is eligible to have the cost of the
913 prescription covered by the health plan. For most of the patient's prescriptions, DSS B indicates that
914 no prior authorization is required by the patient's insurer. However, for one of the prescriptions,
915 erythropoietin (EPO), prior authorization is required by the patient's insurer, Insurance Company IC.

916 Much of the information required for the EPO prior authorization is available from the clinic's EHR
917 system. For the information that is required for the prior authorization but not available in the EHR
918 system, the e-Prescribing system asks David to answer some questions that provide the required
919 information.

920 Based on the information obtained from the EHR system and from David, DSS B is able to conclude
921 that the EPO prescription is medically indicated and therefore approved by Insurance Company IC for
922 coverage. Having received prior authorization, David prescribes the EPO for John, and the e-
923 Prescribing system notifies Insurance Company IC that the authorized EPO prescription will be
924 dispensed in the near future.

925 3.2.2.3 Provision of Critical Laboratory Value Alert to a Physician on Call

926 **Context:** Jane Doe is a 53 year old African-American female with hypertension and diabetes mellitus
927 who is in the hospital following an elective surgical procedure. Doctor David is a general surgeon and
928 the physician on call responsible for Jane's care. David's hospital utilizes an EHR system which uses
929 DSSs to provide decision support capabilities.

930 **Scenario Overview from End-User's Perspective:** Jane appears to be recovering well after her
931 surgery and is seen by David during morning rounds. David orders a complete blood count (CBC)
932 during rounds and proceeds with his other ward duties. When the CBC result is entered into the EHR
933 system, the EHR system utilizes DSS A to check if a clinician should be immediately notified
934 regarding the result. DSS A informs the EHR system that a clinician should in fact be immediately
935 notified, as the hematocrit has been decreasing steadily and has now reached a sufficiently worrisome
936 level. The EHR system therefore pages David with an alert regarding Jane's hematocrit.

937 3.3 Supplemental Scenarios

938 3.3.1 Generic Supplemental Scenarios

939 None defined.

940 3.3.2 Specific Supplemental Scenarios

941 3.3.2.1 Provision of Context-Sensitive Reference Information to a Clinician through an 942 EHR System

943 **Note:** This business scenario has been adapted from the May 2006 committee-level DSTU ballot
944 materials for the Infobutton Communication Standard.

945 **Context:** Jane Doe is a 15 year old Caucasian female with a rare disease known as Camurati-
946 Engelmann Disease. Doctor David is an internist and Jane's primary care clinician. David's practice
947 utilizes an EHR system which uses DSSs to provide context-sensitive reference information.

948 **Scenario Overview from End-User's Perspective:** Jane checks into David's clinic. When David
949 reviews Jane's problem list in the EHR system, there are links next to each problem for retrieving
950 context-sensitive reference information regarding the problem.

951 David is unfamiliar with Camurati-Engelmann Disease, so he clicks on the information link next to the
952 problem. David is then presented with a screen with a list of questions related to the disease that he
953 may be interested in (e.g., "What is the definition of Camurati-Engelmann Disease?", "How do I
954 diagnose Camurati-Engelmann Disease?", and "How do I treat Camurati-Engelmann Disease?").

955 David clicks on the "What is the definition of Camurati-Engelmann Disease?" In response, David
956 receives back a screen containing URL links to context-sensitive information resources. An example
957 context-sensitive information resource is the "Overview and definition" section of Camurati-
958 Engelmann Disease in an online medical textbook.

959

960 4 Service Definition and Dependencies

961 Section 4.1 contains material that is common to all HSSP Service Functional Models. Section 4.2
962 provides a concise statement of scope, assumptions and dependencies.

963

964 4.1 Service Definition Principles

965 The high level principles regarding service definition that have been adopted by the Healthcare
966 Services Specification Project are as follows:

- 967 ➤ Service Specifications shall be well defined and clearly scoped and with well understood
968 requirements and responsibilities.
- 969 ➤ Services should have a unity of purpose (e.g., fulfilling one domain or area) but services
970 themselves may be composable.
- 971 ➤ Services will be specified sufficiently to address functional, semantic, and structural
972 interoperability.
- 973 ➤ It must be possible to replace one conformant service implementation with another meeting the
974 same service specification while maintaining functionality of the system.

975 A Service at the Functional Model level is regarded as a system component; the meaning of the term
976 “(system) component” in this context is consistent with UML usage.⁹ A component is a modular unit
977 with well-defined interfaces that is replaceable within its environment. A component can always be
978 considered an autonomous unit within a system or subsystem. It has one or more provided and/or
979 required interfaces, and its internals are hidden and inaccessible other than as provided by its
980 interfaces.

981 Each Service’s Functional Model defines the interfaces that the service exposes to its environment, and
982 the service’s dependencies on services provided by other components in its environment.
983 Dependencies in the Functional Model relate to services that have or may in the future have a
984 Functional Model at a similar level; dependencies on low-level utility services should not be included,
985 as that level of design is not in scope for the Functional Model.

986 The manner in which services and interfaces are deployed, discovered, etc. is outside the scope of the
987 Functional Model. All other interactions within the scope of the scenarios identified above are in the
988 scope of the Functional Model.

989 Reference may be made to other specifications for interface descriptions, for example where an
990 interface is governed by an existing standard.

991 **4.2 Overall Assumptions, Dependencies, and/or Scope Exclusions**

992 As discussed in Section 2.4.3, it is assumed that a RLUS may be used by many clients to obtain the
993 data required by a DSS. However, this is not considered to be a dependency, as the use of a RLUS is
994 not required by a DSS.

995 With regard to items being specifically excluded from the scope of this specification, please refer to
996 Section 2.1.3 (Overall Potential Scope of the Service) and Section 2.3.6 (Service Aspects to be Defined
997 in Future Specifications).

⁹ It is expected that services will be defined, in response to the OMG RFP process, as UML components. However, that level of design is outside the scope of the Functional Model.

998 **5 Detailed Functional Model for each Interface**

- 999 ➤ Note that each “capability” may result in one or more individual operations in the technical
1000 specification resulting from an RFP submission.

1001

1002 **5.1 Meta-data Discovery Interface**

1003 **5.1.1 List Scoping Entities Supported by Service**

Description	Lists the scoping entities supported by the service.
Precondition	None
Inputs	None
Outputs	<ul style="list-style-type: none">List of scoping entities supported by the service. Data returned for each scoping entity consist of:<ul style="list-style-type: none">➤ Identifier of scoping entity
Post-conditions	None
Business exception conditions	
Aspects left to OMG RFP submitters	<ul style="list-style-type: none">Whether and how to order scoping entities in the output
Relationship to levels of conformance (or other patterns)	Supported by all functional profiles
Notes	

1004

1005 **5.1.2 Describe Scoping Entity**

Description	Describes a scoping entity supported by the service.
Precondition	Scoping entity specified is supported by the service.
Inputs	<ul style="list-style-type: none">• Scoping entity identifier
Outputs	<ul style="list-style-type: none">• Name of scoping entity• Description of scoping entity
Post-conditions	None
Business exception conditions	<ul style="list-style-type: none">• The scoping entity is not recognized by the service
Aspects left to OMG RFP submitters	
Relationship to levels of conformance (or other patterns)	Supported by all functional profiles
Notes	

1006

5.1.3 List Semantic Signifiers Supported by Service

Description	Lists the semantic signifiers supported by the service.
Precondition	None
Inputs	<ul style="list-style-type: none"> • (Optional) List of semantic signifier types of interest. <p>Possible semantic signifier types could include HL7 RMIMs, HL7 Templates, OpenEHR archetypes, Dutch National IT Institute for Healthcare Care Information Models, etc.</p> <ul style="list-style-type: none"> • (Optional) List of contexts in which a semantic signifier is used. <p>Possible contexts consist of: (1) used by knowledge modules to specify how evaluation results will be returned; (2) used by knowledge modules to specify how required data should be provided; (3) used by knowledge modules to specify how data requirement query parameters are expressed; (4) used by knowledge modules to specify the information model used by a complex knowledge module trait; (5) used by a knowledge module trait requirement; (6) used by a knowledge module evaluation result requirement; (7) used by a knowledge module data requirement superset requirement; (8) used by a knowledge module data meta-requirement; (9) used by a knowledge module requirement aggregate; (10) used by a knowledge module requirement not otherwise classified; (11) used by a semantic profile not otherwise classified; and (11) used by a service profile not otherwise classified.</p>
Outputs	<ul style="list-style-type: none"> • List of semantic signifiers supported by the DSS, grouped by context of use. If optional constraint parameters specified, only semantic signifiers fulfilling the constraint parameters are returned. <p>Data returned for each semantic signifier consist of:</p> <ul style="list-style-type: none"> ➤ Identifier of the semantic signifier's scoping entity ➤ Semantic signifier identifier (unique within scoping entity) ➤ If a semantic signifier is being listed under context 2 above (specification of how required data should be provided), each semantic signifier is accompanied by the unique sets of semantic signifiers used by individual knowledge modules to specify the information models that can be used to query for the required data
Post-conditions	None
Business exception conditions	
Aspects left to OMG RFP submitters	<ul style="list-style-type: none"> • Whether and how to order semantic signifiers in the output

Relationship to levels of conformance (or other patterns)	Supported by all functional profiles
Notes	

1008

1009 **5.1.4 Describe Semantic Signifier**

Description	Describes a semantic signifier supported by the service.
Precondition	Specified semantic signifier is supported by the service.
Inputs	<ul style="list-style-type: none"> • Identifier of the semantic signifier's scoping entity • Semantic signifier identifier (unique within scoping entity)
Outputs	<ul style="list-style-type: none"> • Name of semantic signifier • Type of semantic signifier • Description of semantic signifier • (optional) Computable definition of semantic signifier (type-dependent)
Post-conditions	None
Business exception conditions	<ul style="list-style-type: none"> • The semantic signifier is not recognized by the service
Aspects left to OMG RFP submitters	<ul style="list-style-type: none"> • Whether to require a DSS to be capable of providing a computable definition of all semantic signifiers supported by the service.
Relationship to levels of conformance (or other patterns)	Supported by all functional profiles
Notes	The computable definition of a semantic signifier could potentially be obtained from a semantic signifier service to be defined by the HSSP. In this case, the DSS could call on this semantic signifier service to obtain the definition of the semantic signifier for the client. Also, a client could potentially obtain the computable definition of a semantic signifier outside the context of the DSS. For example, the computable definition of a HL7 RMIM could be obtained through the HL7 Web site.

1010

1011 **5.1.5 List Knowledge Module Traits Supported by Service**

Description	Lists the knowledge module traits supported by the service.
Precondition	None
Inputs	None
Outputs	<ul style="list-style-type: none">• List of knowledge module traits supported by the service. Data returned for each knowledge module trait consist of:<ul style="list-style-type: none">➤ Identifier of knowledge module trait’s scoping entity➤ Knowledge module trait identifier and version (unique within scoping entity)
Post-conditions	None
Business exception conditions	
Aspects left to OMG RFP submitters	<ul style="list-style-type: none">• Whether and how to order traits in the output
Relationship to levels of conformance (or other patterns)	Supported by all functional profiles
Notes	

1012

1013 **5.1.6 Describe Knowledge Module Trait**

Description	Describes a knowledge module trait supported by the service.
Precondition	Knowledge module trait specified is referenced by the service.
Inputs	<ul style="list-style-type: none"> • Identifier of knowledge module trait's scoping entity • Knowledge module trait identifier and version (unique within scoping entity)
Outputs	<ul style="list-style-type: none"> • Name of knowledge module trait • Description of trait • Whether a change in the trait requires a change in the version of the knowledge module possessing the trait • Data type of trait value (for simple knowledge module traits) or semantic signifier of information model used to express trait (for complex traits) • List of zero or more trait criteria that a client system can use at design time or at run time to select among knowledge modules that possess the trait <p>Data returned for each trait criterion consist of:</p> <ul style="list-style-type: none"> ➤ Identifier of trait criterion (unique within trait) ➤ Name of criterion ➤ Description of criterion ➤ Data type of trait criterion value
Post-conditions	None
Business exception conditions	<ul style="list-style-type: none"> • The knowledge module trait is not recognized by the service
Aspects left to OMG RFP submitters	
Relationship to levels of conformance (or other patterns)	Supported by all functional profiles

Notes	<p>Example:</p> <ul style="list-style-type: none"> - Trait name = last review date - Description = date knowledge module was last reviewed for accuracy - Data type of trait value = HL7 V3 Point in Time - Change in the trait requires a change in the version of the knowledge module possessing the trait: false - List of two search criteria that a client can use to select among knowledge modules that possess the trait: <ul style="list-style-type: none"> > Trait criterion 1: <ul style="list-style-type: none"> - Identifier = ReviewedWithinLastXDays - Name = Module reviewed within designated number of days - Description = This criterion assesses whether the knowledge module has been reviewed within the designated number of days. - Data type of trait criterion value = HL7 V3 Integer Number > Trait criterion 2: <ul style="list-style-type: none"> - Identifier = ReviewedOnOrAfter - Name = Module reviewed on or after specified date - Description = This criterion assesses whether the knowledge module has been reviewed on or after the specified date - Data type of trait criterion value = HL7 V3 Point in Time
--------------	---

1015 **5.1.7 List Profiles Supported by Service**

Description	Lists the functional and/or semantic profiles supported by the service. The type of profile may optionally be specified to restrict the result returned.
Precondition	None
Inputs	<ul style="list-style-type: none"> • (Optional) List of profile types of interest. <p>The possible profile types are enumerated in the service's computational meta-model (Figure 4).</p>
Outputs	<ul style="list-style-type: none"> • List of profiles supported by the DSS, grouped by type of profile. <p>If the types of profiles of interest are specified, returns only those profiles of the type(s) specified. Data returned for each profile consist of:</p> <ul style="list-style-type: none"> ➤ Identifier of the profile's scoping entity ➤ Profile identifier and version (unique within scoping entity)
Post-conditions	None
Business exception conditions	<ul style="list-style-type: none"> • The profile type specified as a query condition is not recognized
Aspects left to OMG RFP submitters	<ul style="list-style-type: none"> • Whether and how to order profiles in the output
Relationship to levels of conformance (or other patterns)	Supported by all functional profiles
Notes	

1016

1017 **5.1.8 Describe Profile**

Description	Describes a profile supported by the service.
Precondition	Profile specified is supported by the service.
Inputs	<ul style="list-style-type: none"> • Identifier of the profile's scoping entity • Profile identifier and version (unique within scoping entity)
Outputs	<ul style="list-style-type: none"> • Profile name • Profile type <p>The possible profile types are enumerated in the service's computational meta-model (Figure 4).</p> <ul style="list-style-type: none"> • Profile description • Additional data specific to the type of profile. <p>For <u>conformance profiles</u> → A list of one or more supported functional profiles, one or more supported semantic profiles, and zero or more supported service profiles not otherwise classified.</p> <p>For <u>functional profiles</u> → A list of supported service operations.</p> <p>For <u>semantic profiles of the knowledge module requirement type</u> → A list of the knowledge module requirements with which all knowledge modules hosted by the service conform, and a list of the knowledge module requirements with which at least one of the knowledge modules hosted by the service conforms.</p> <p>For <u>semantic profiles not otherwise classified</u> and for <u>service profiles not otherwise classified</u> → A computational definition (optional).</p>
Post-conditions	None
Business exception conditions	<ul style="list-style-type: none"> • The profile is not recognized by the service
Aspects left to OMG RFP submitters	
Relationship to levels of conformance (or other patterns)	Supported by all functional profiles
Notes	

1018 **5.1.9 List Knowledge Module Requirements Supported by Service**

Description	Lists the knowledge module requirements supported by the service. The type of requirement may optionally be specified to restrict the result returned.
Precondition	None
Inputs	<ul style="list-style-type: none"> • (Optional) List of knowledge module requirement types of interest. <p>The possible requirement types are enumerated in the service's computational meta-model (Figure 4).</p>
Outputs	<ul style="list-style-type: none"> • List of knowledge module requirements supported by the DSS, grouped by requirement type. <p>If the types of requirements of interest are specified, returns only those requirements of the type(s) specified. Data returned for each knowledge module requirement consist of:</p> <ul style="list-style-type: none"> ➤ Identifier of the requirement's scoping entity ➤ Requirement identifier and version (unique within scoping entity)
Post-conditions	None
Business exception conditions	<ul style="list-style-type: none"> • The knowledge module requirement type specified as a query condition is not recognized
Aspects left to OMG RFP submitters	<ul style="list-style-type: none"> • Whether and how to order requirements in the output
Relationship to levels of conformance (or other patterns)	Supported by all functional profiles
Notes	

1019

5.1.10 Describe Knowledge Module Requirement

Description	Describes a knowledge module requirement supported by the service.
Precondition	Knowledge module requirement specified is supported by the service.
Inputs	<ul style="list-style-type: none"> • Identifier of the knowledge module requirement's scoping entity • Requirement identifier and version (unique within scoping entity)
Outputs	<ul style="list-style-type: none"> • Name of knowledge module requirement • Type of knowledge module requirement <p>The possible knowledge module requirement types are enumerated in the service's computational meta-model (Figure 4).</p> <ul style="list-style-type: none"> • Description of the knowledge module requirement • Additional data specific to the type of knowledge module requirement. <p>For <u>knowledge module trait requirements</u> → A list of the knowledge module traits that will or may be associated with all knowledge modules claiming conformance to the requirement. Traits are identified by the identifier of the trait's scoping entity, the trait identifier (unique within the scoping entity), and the trait version. The requirement also specifies if the trait is required or optional for knowledge modules claiming conformance to the requirement.</p> <p>For <u>knowledge module evaluation result requirements</u> → The semantic signifier of the information model that will be used by all knowledge modules claiming conformance to the requirement to return evaluation results.</p> <p>For <u>knowledge module data requirement superset requirements</u> → A list of the complete set of semantic signifiers that can be used by knowledge modules claiming conformance to the requirement when specifying how required data are provided to the DSS. Each of these semantic signifiers is associated with zero or more semantic signifiers representing the information models that can be used to express query parameters for retrieving the required data. Also, this type of requirement specifies whether a knowledge module claiming conformance to the requirement may possess data requirement groups that contain other data requirement groups through the use of the Composition class. This type of requirement also specifies whether all data requirements for a KM must be contained within a single data requirement group.</p> <p>For <u>knowledge module data meta-requirements</u> → A specification of the exact set of data requirement groups to be required by knowledge modules claiming conformance to the requirement.</p> <p>For <u>knowledge module requirement aggregates</u> → A list of one or more knowledge module requirements which must be supported by knowledge modules claiming conformance to the aggregate requirement.</p> <p>For <u>knowledge module requirements not otherwise classified</u> → A computational definition (optional).</p>

Post-conditions	None
Business exception conditions	<ul style="list-style-type: none"> The knowledge module requirement is not recognized by the service
Aspects left to OMG RFP submitters	
Relationship to levels of conformance (or other patterns)	Supported by all functional profiles
Notes	

1021

1022 5.2 Query Interface

1023 5.2.1 Find Knowledge Modules

Description	Returns knowledge modules fulfilling client search criteria. If no search criteria are specified, returns a list of all knowledge modules hosted by the service.
Precondition	None
Inputs	<ul style="list-style-type: none"> • (Optional) Knowledge module requirements supported, organized using the logical operators AND, OR, and NOT. • (Optional) Knowledge module trait criteria, organized using the logical operators AND, OR, and NOT. • (Optional) Knowledge module statuses that allow a knowledge module to be considered. <p>The possible knowledge module statuses are enumerated in the service's computational meta-model (Figure 4).</p> <ul style="list-style-type: none"> • (Optional) A list of semantic signifiers specifying the information models that can be used to return evaluation results. • (Optional) A list of semantic signifiers specifying the information models that are available for providing data, each accompanied by semantic signifiers specifying the information models that can be used for querying for that data. If this search parameter is specified, only those knowledge modules whose data requirements can be fulfilled by the data specified are returned. • (Optional) Whether to restrict the result to knowledge modules which do not have data requirement groups that are composed of other data requirement groups. • (Optional) A list of related knowledge modules. Retrieved knowledge modules should be related to or be the same as at least one of these knowledge modules. Optionally, the type of relationship from one of the specified knowledge modules to a returned knowledge module can be specified. <p>Note that there is an implicit AND between input categories.</p>
Outputs	<ul style="list-style-type: none"> • List of knowledge modules fulfilling the search criteria. <p>Data returned for each knowledge module consist of:</p> <ul style="list-style-type: none"> ➤ The identifier of the knowledge module's scoping entity ➤ The identifier and version of the knowledge module (unique within scoping entity)
Post-conditions	None

Business exception conditions	<ul style="list-style-type: none"> • A knowledge module requirement specified as a query condition is not recognized. • A knowledge module trait specified as a query condition is not recognized. • A knowledge module status specified as a query condition is not recognized. • A semantic signifier specified as a query condition is not recognized.
Aspects left to OMG RFP submitters	<ul style="list-style-type: none"> • The codes to use for specifying relationships between knowledge modules • Whether and how to order knowledge modules in the output
Relationship to levels of conformance (or other patterns)	Supported by all functional profiles
Notes	

5.2.2 Get Knowledge Module Description

Description	Returns a description of the specified knowledge module. Clients may optionally restrict the sections of the knowledge module that are returned as descriptions.
Precondition	The specified knowledge module exists
Inputs	<ul style="list-style-type: none"> • The identifier of the knowledge module's scoping entity • The identifier and version of the knowledge module (unique within scoping entity) • (Optional) List of the sections of interest within the knowledge module. <p>The sections that may be specified consist of: supported knowledge module requirements, status, traits, and related knowledge modules.</p>
Outputs	<ul style="list-style-type: none"> • Specified sections of the knowledge module of interest. If no sections specified, all sections returned.
Post-conditions	None
Business exception conditions	<ul style="list-style-type: none"> • The requested knowledge module does not exist.
Aspects left to OMG RFP submitters	
Relationship to levels of conformance (or other patterns)	Supported by all functional profiles
Notes	

1026 **5.2.3 Get How Knowledge Module Evaluation Results Will be Returned**

Description	Returns a specification of the information model that will be used by the knowledge module when returning an evaluation result.
Precondition	The specified knowledge module exists
Inputs	<ul style="list-style-type: none"> • The identifier of the knowledge module's scoping entity • The identifier and version of the knowledge module (unique within scoping entity)
Outputs	<ul style="list-style-type: none"> • The semantic signifier of the information model that will be used to return the evaluation result.
Post-conditions	None
Business exception conditions	<ul style="list-style-type: none"> • The requested knowledge module does not exist.
Aspects left to OMG RFP submitters	
Relationship to levels of conformance (or other patterns)	Supported by all functional profiles
Notes	

1027 **5.2.4 Get Knowledge Module Data Requirements**

Description	Returns a specification of the data required by the knowledge module for conducting an evaluation.
Precondition	The specified knowledge module exists
Inputs	<ul style="list-style-type: none">• The identifier of the knowledge module’s scoping entity• The identifier and version of the knowledge module (unique within scoping entity)
Outputs	<ul style="list-style-type: none">• Specification of the data required by the knowledge module for conducting an evaluation. Expressed in terms of data requirement groups and their constituent data requirement groups and/or data requirement items.
Post-conditions	None
Business exception conditions	<ul style="list-style-type: none">• The requested knowledge module does not exist.
Aspects left to OMG RFP submitters	
Relationship to levels of conformance (or other patterns)	Supported by all functional profiles
Notes	

1028

5.2.5 Get Knowledge Module Data Requirements Given Available Data

Description	Returns a specification of the data required by the knowledge module for conducting an evaluation, given the data available to the client. The operation determines whether the data available to the client are sufficient and informs the client of any data requirements that are not met. Data query parameters are specified in terms of the query parameter information models supported by the client.
Precondition	The specified knowledge module exists
Inputs	<ul style="list-style-type: none"> • The identifier of the knowledge module's scoping entity • The identifier and version of the knowledge module (unique within scoping entity) • The data available to the client, specified in terms of a list of semantic signifiers identifying the information models available for providing data. Each of these semantic signifiers should be accompanied by zero or more semantic signifiers specifying the information models that can be used to specify the data query parameters.
Outputs	<ul style="list-style-type: none"> • Whether the data available to the client can fulfill all data requirements for the knowledge module • A list of any data deficiencies, specified in terms of the identifiers of any knowledge module data requirement groups whose data needs cannot be fulfilled given the data available to the client. • Specification of the data that are 1) required by the knowledge module for conducting an evaluation and are 2) available to the client. Expressed in terms of data requirement groups and their constituent data requirement groups and/or data requirement items. A data requirement group is included in the output only if its data needs can be fulfilled given the data available to the client.
Post-conditions	None
Business exception conditions	<ul style="list-style-type: none"> • The requested knowledge module does not exist.
Aspects left to OMG RFP submitters	
Relationship to levels of conformance (or other patterns)	Supported by all functional profiles

Notes	
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1030

1031 5.3 Evaluation Interface

1032 5.3.1 Get Knowledge Module Evaluation Result

Description	Evaluates the data provided by the client using one or more knowledge modules and returns the result(s) of the evaluation.
Precondition	<p>The specified knowledge module(s) exist</p> <p>The client is providing the data required by the knowledge module. The required data are identified using the Get Knowledge Module Data Requirements operation specified above.</p>
Inputs	<ul style="list-style-type: none"> • The client's time zone. • One or more knowledge modules to use for the evaluation. <p>Each knowledge module is identified by the scoping entity identifier, knowledge module identifier, and knowledge module version.</p> <ul style="list-style-type: none"> • The data required by each of the knowledge modules specified. These data should be provided as a list of responses to data requirement items. Each response to a data requirement item should consist of: <ul style="list-style-type: none"> ➤ The identifier of the knowledge module for which the data are required (each knowledge module is identified by the scoping entity identifier, knowledge module identifier, and knowledge module version). ➤ The identifier of the data requirement item ➤ The contents of the data requirement item, in the format specified by the knowledge module using semantic signifiers <p>In the case that the same data are needed by multiple knowledge modules as data requirement items, the contents of the data requirement items can be provided once and identified as fulfilling the needs of multiple knowledge modules.</p>
Outputs	<ul style="list-style-type: none"> • For each knowledge module specified, evaluation results are returned in the format specified by the knowledge module's semantic signifier for evaluation result semantics.
Post-conditions	None
Business exception conditions	<ul style="list-style-type: none"> • The requested knowledge module does not exist. • Required data were not provided in the correct format. • Required data not provided. This exception specifies the data requirement group(s) for which data were required but not provided. • An unexpected error occurred during the evaluation process.

Aspects left to OMG RFP submitters	
Relationship to levels of conformance (or other patterns)	Supported by all functional profiles
Notes	

1033

1034 **5.3.2 Get Knowledge Module Evaluation Result as if it was the Specified Time**

1035 This operation is identical to the Get Knowledge Module Evaluation Result operation, except that the
1036 client is able to specify any time in the past or future as the time at which the evaluation occurs.

1037 This method is considered an optional method, and is therefore supported only by the Advanced Time
1038 Handling DSS Functional Profile.

1039

1040 **6 Profiles**

1041 As discussed in Section 2.3.2, this specification is designed as a generic service framework which can
1042 be adapted in various ways to meet clients' clinical decision support needs. While this flexibility is
1043 desirable, too much flexibility could make it more difficult to implement a DSS and/or to achieve plug-
1044 and-play interoperability among multiple DSSs. The specification of profiles allows the service to be
1045 constrained to the degree required for implementation and interoperability.

1046 Of note, it is envisaged that many profiles will be defined after the adoption of this SFM. Some of
1047 these profiles may be specified as formal, balloted profiles defined by standards development
1048 organizations such as HL7 and OMG, while other profiles may be specified as informal profiles
1049 defined by individual vendors, institutions, geographic regions, and other domains.

1050 **6.1 Profile Types**

1051 As defined in Section 2.3.2 and delineated in the computational meta-model of the service (**Figure 4** in
1052 Section 2.3.4), several types of profiles can be defined. **Table 6** summarizes the types of profiles that
1053 may be specified. Of note, sample, non-normative profiles have been specified in Section 14.4 of
1054 **Appendix II** for the purposes of illustration.

1055 **Table 6.** Types of profiles that may be specified for a DSS

Profile Type	Description
Functional profile	Specifies the list of supported service operations
Semantic profile, knowledge module requirement type	Specifies that all knowledge modules hosted by the service fulfill a specified set of knowledge module requirements, and/or that at least one knowledge module hosted by the service fulfills a specified set of knowledge module requirements.
Semantic profile, not otherwise classified	Specifies the semantic content of a DSS in a manner that is not otherwise classified.
Service profile, not otherwise classified	Specifies a constraint on a DSS in a manner that is not otherwise classified.
Conformance profile	Specifies a list of one or more supported functional profiles, one or more supported semantic profiles, and zero or more supported service profiles of a type that is not otherwise classified.

1056

1057 **6.2 Knowledge Module Requirement Types**

1058 As just defined in Section 6.1, a semantic profile of the knowledge module requirement type is defined
1059 in terms of the knowledge module requirements supported by some or all of a DSS's knowledge
1060 modules. As defined in Section 2.3.4.3.1 and delineated in the computational meta-model of the
1061 service (**Figure 4** in Section 2.3.4), several types of knowledge module requirements can be defined.

1062 **Table 7** summarizes the types of knowledge module requirements that may be specified. Of note,
1063 sample, non-normative knowledge module requirements have been specified in Section 14.5 of
1064 **Appendix II** for the purposes of illustration.

1065 **Table 7.** Types of knowledge module requirements that may be specified for a knowledge module

Knowledge Module Requirement Type	Description
Knowledge module trait requirement	Specifies the traits that are used to describe the knowledge module, as well as how searches can be performed against those traits.
Knowledge module evaluation result requirement	Specifies the semantic signifier of the information model that will be used by all knowledge modules claiming conformance to the requirement to return evaluation results.
Knowledge module data requirement superset requirement	Specifies a list of the complete set of semantic signifiers that can be used by knowledge modules claiming conformance to the requirement when specifying how required data are provided to the DSS. Each of these semantic signifiers is associated with zero or more semantic signifiers representing the information models that can be used to express query parameters for retrieving the required data. Also, this type of requirement specifies whether a knowledge module claiming conformance to the requirement may possess data requirement groups that contain other data requirement groups through the use of the Composition class. This type of requirement also specifies whether all data requirements for a knowledge module must be contained within a single data requirement group.
Knowledge module data meta-requirement	Specifies the exact set of data requirement groups to be required by knowledge modules claiming conformance to the requirement
Knowledge module requirement aggregate	Specifies one or more knowledge module requirements which must be supported by knowledge modules claiming conformance to the aggregate requirement
Knowledge module requirement, not otherwise classified	Specifies a requirement for a knowledge module in a manner that is not otherwise classified.

1066

1067 **6.3 Profiles and Knowledge Module Requirements Specified as a Part of this**
1068 **SFM**

1069 This SFM specifies several profiles and knowledge module requirements to ensure a minimum level of
1070 interoperability among DSSs. This section defines these normative specifications, which consist of
1071 two functional profiles (the Core DSS Functional Profile and the Advanced Time Handling DSS
1072 Functional Profile), one knowledge module trait requirement (the Minimum DSS Knowledge Module
1073 Trait Requirement), one semantic profile of the knowledge module requirement type, and one
1074 conformance profile (the Minimum HL7 DSS Conformance Profile). These specifications are defined
1075 below.

1076 **6.3.1 Core DSS Functional Profile, Version 1.0**

1077 To claim conformance to the HL7 Core DSS Functional Profile, version 1.0, a DSS must implement
1078 and support all service operations defined in Section 5, except for the “Get Knowledge Module
1079 Evaluation Result as if it was the Specified Time” operation (Section 5.3.2).

1080 **6.3.2 Advanced Time Handling DSS Functional Profile, Version 1.0**

1081 To claim conformance to the HL7 Advanced Time Handling DSS Functional Profile, version 1.0, a
 1082 DSS must implement and support all service operations defined in Section 5, including the “Get
 1083 Knowledge Module Evaluation Result as if it was the Specified Time” operation (Section 5.3.2).

1084 **6.3.3 Minimum Meta-Data DSS Semantic Profile, Version 1.0**

1085 This profile is a semantic profile of the knowledge module requirement type. To claim conformance to
 1086 the HL7 Minimum Meta-Data DSS Semantic Profile, version 1.0, all knowledge modules hosted by a
 1087 DSS must fulfill the Minimum DSS Knowledge Module Trait Requirement, which is specified next.

1088 **6.3.4 Minimum DSS Knowledge Module Trait Requirement, Version 1.0**

1089 To claim conformance to this knowledge module trait requirement, a knowledge module must support
 1090 the following traits and trait criteria (all traits shall be considered mandatory). Note that HL7-I for the
 1091 scoping entity refers to HL7 International.

1092 **6.3.4.1 Knowledge Module Traits Required by Knowledge Module Requirement**

Scoping Entity	Trait Identifier*	Description	Data Type or Semantic Signifier	Change Requires KM Version Change
HL7-I	StewardOrganization	The organization acting as the steward of the KM	HL7 V3 Organization entity	No
HL7-I	CreationDate	Date KM was first created	HL7 V3 Point in Time	No
HL7-I	LastReviewDate	Date when KM was last reviewed for accuracy	HL7 V3 Point in Time	No
HL7-I	AuthorList	A list of the KM's authors	List of HL7 V3 Person entities	No
HL7-I	KeywordListEnglishFree Text	A list of English free text keywords that characterize the KM. May be empty.	List of HL7 V3 Character Strings	No
HL7-I	KeywordListCodedValue	A list of keywords that characterize the KM, represented using coded values from one or more vocabularies. May be empty.	List of HL7 V3 Coded Values	No
HL7-I	Purpose	The purpose of a KM in English text (intended for a medical informaticist)	HL7 V3 Character String	No
HL7-I	Explanation	An English text explanation of how the KM uses the required data to generate evaluation results (intended for a medical informaticist)	HL7 V3 Character String	No

1093 *All traits in this table have a version of 1.0

1094 6.3.4.2 Knowledge Module Trait Criteria that Must be Available to Query for KMs
1095 Based on Trait

Scoping Entity	Trait Identifier*	Criterion Identifier	Description	Data Type
HL7-I	Steward Organization	StewardOrganization Identifier	Specifies that steward organization must have the identifier specified	HL7 V3 Instance Identifier
HL7-I	Steward Organization	StewardOrganizationName Contains	Specifies that steward organization name must contain the string specified	HL7 V3 Character String
HL7-I	LastReviewDate	ReviewedOnOrAfter	Specifies that LastReviewDate must have been on or after the specified date	HL7 V3 Point in Time
HL7-I	LastReviewDate	ReviewedWithinLastXDays	Specifies that LastReviewDate must have occurred within specified number of days	HL7 V3 Integer Number
HL7-I	KeywordList EnglishFreeText	KeywordContains	Specifies that at a keyword must contain the specified string	HL7 V3 Character String
HL7-I	KeywordList CodedValue	KeywordExists	Specifies that the specified code exists as a keyword	HL7 V3 Coded Value
HL7-I	KeywordList CodedValue	KeywordOrKeyword DescendantExists	Specifies that the specified code or a descendant concept exists as a keyword	HL7 V3 Coded Value

1096 *All traits in this table have a version of 1.0

1097 **6.3.5 Minimum HL7 DSS Conformance Profile, Version 1.0**

1098 To claim conformance to this profile, a DSS must be conformant with the HL7 Core DSS Functional
1099 Profile, version 1.0 (Section 6.3.1) and the HL7 Minimum Meta-Data DSS Semantic Profile, version
1100 1.0 (Section 6.3.3).

1101 **6.4 Minimal Requirement for Claiming Conformance to HL7 DSS Standard**

1102 To claim conformance to the HL7 DSS standard, a DSS must be conformant with the Minimum HL7
1103 DSS Conformance Profile, version 1.0 (Section 6.3.5).

1104 **6.5 Future Specifications of Profiles and Knowledge Module Requirements**

1105 As discussed in Section 2.3.6, it is anticipated that many more semantic profiles and knowledge
1106 module requirements will be specified in the future. These specifications are expected to take the form
1107 of HL7-defined specifications as well as specifications defined by other entities, such as individual
1108 vendors.

1109 **7 Use Scenario Interaction Details (Informative Content)**

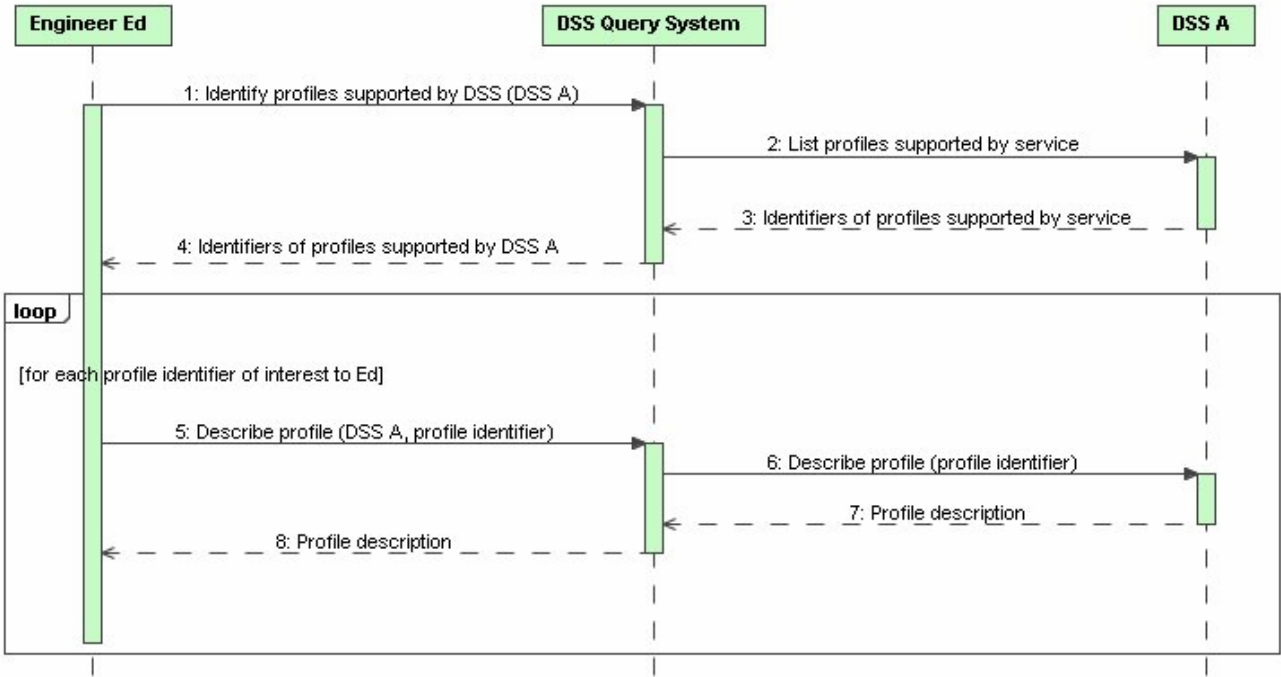
1110 This section elaborates on the business scenarios described in Section 3 by describing the dynamics of
1111 the service from an architectural viewpoint. Note that, as with Section 3, the contents of this section
1112 are non-normative in nature. Specifically, this section illustrates how a DSS and its knowledge
1113 modules *could* be implemented and used, rather than on how they *should* or *must* be used.

1114 **7.1 Primary Scenarios**

1115 **7.1.1 Generic Primary Scenarios**

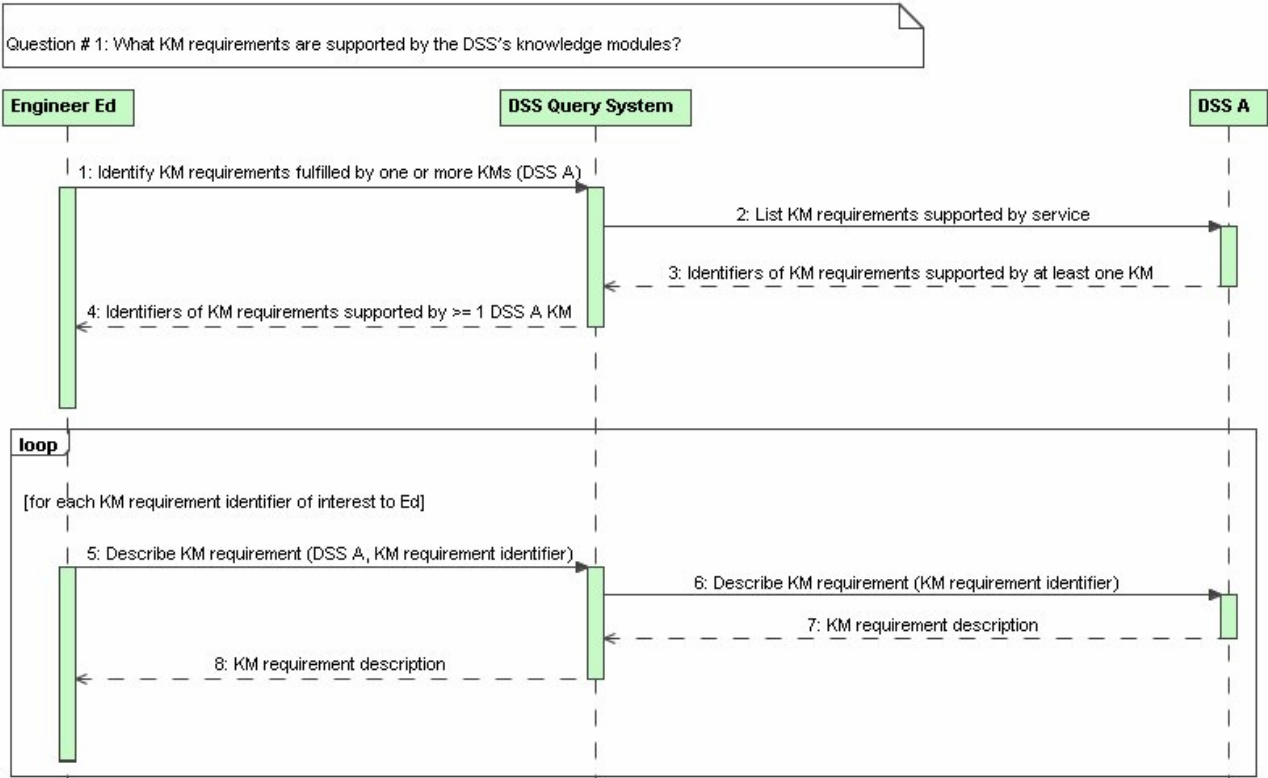
1116 This section outlines scenarios that cover the generic steps involved in making use of a DSS to meet
1117 decision support needs.

1118 **7.1.1.1 Identification of DSS Capabilities**

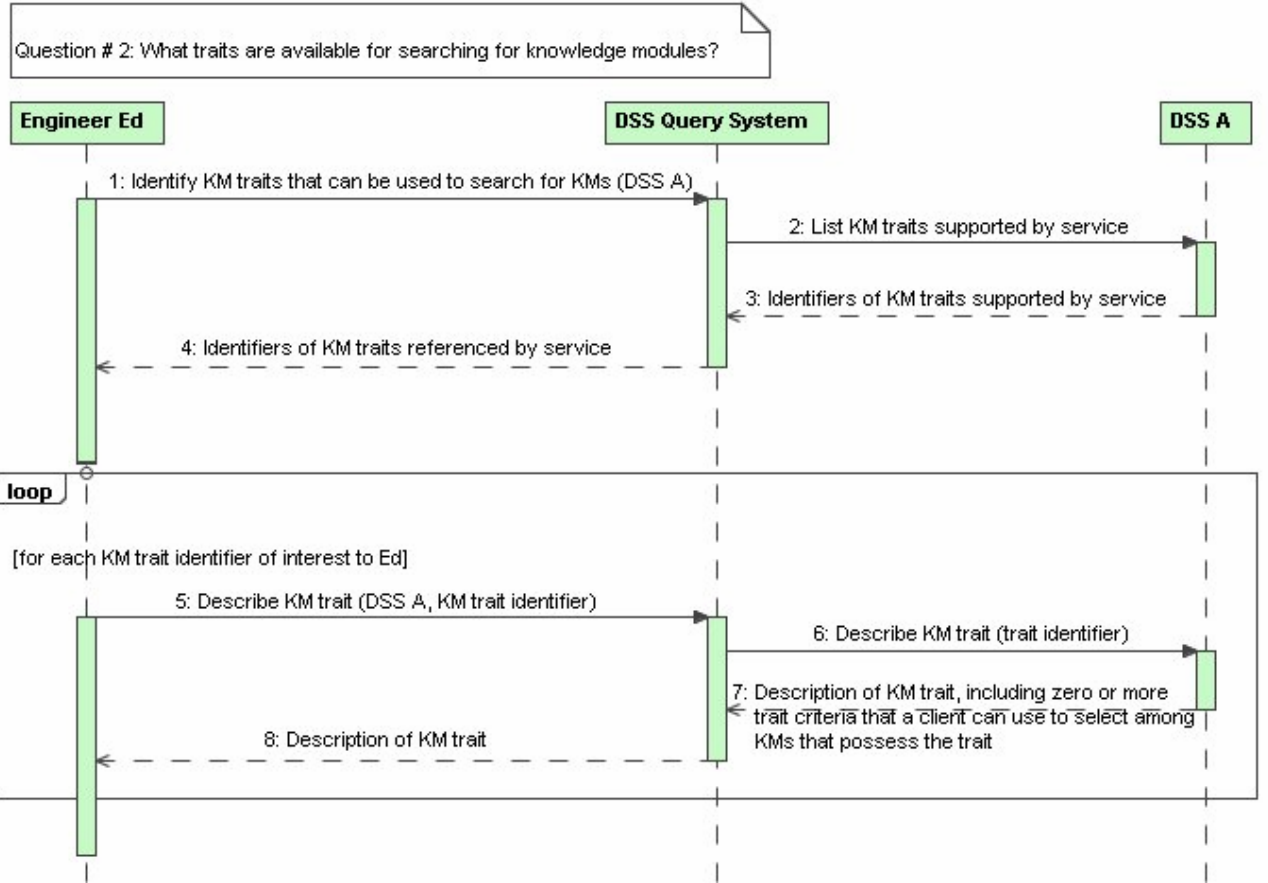


1119

1120 7.1.1.2 Identification of Knowledge Modules of Interest

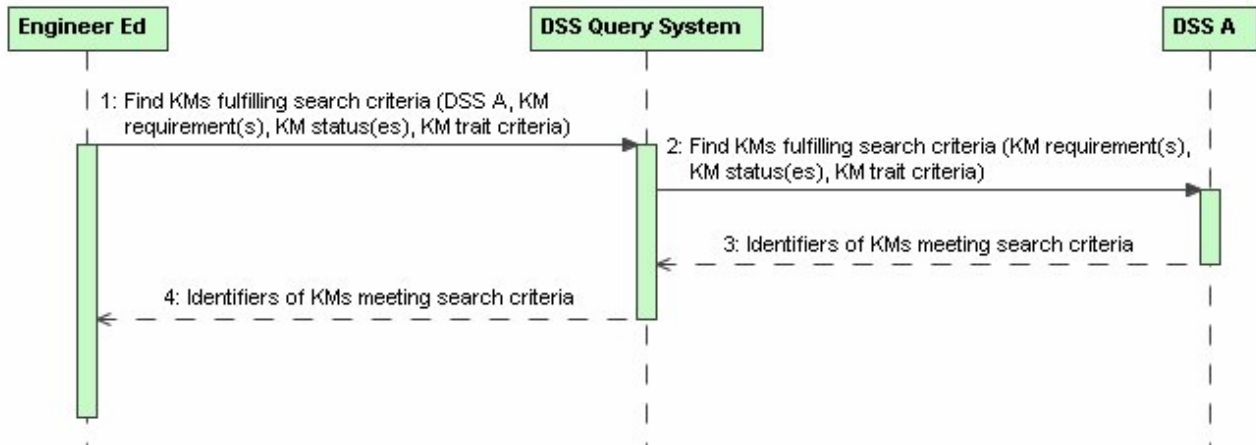


1121

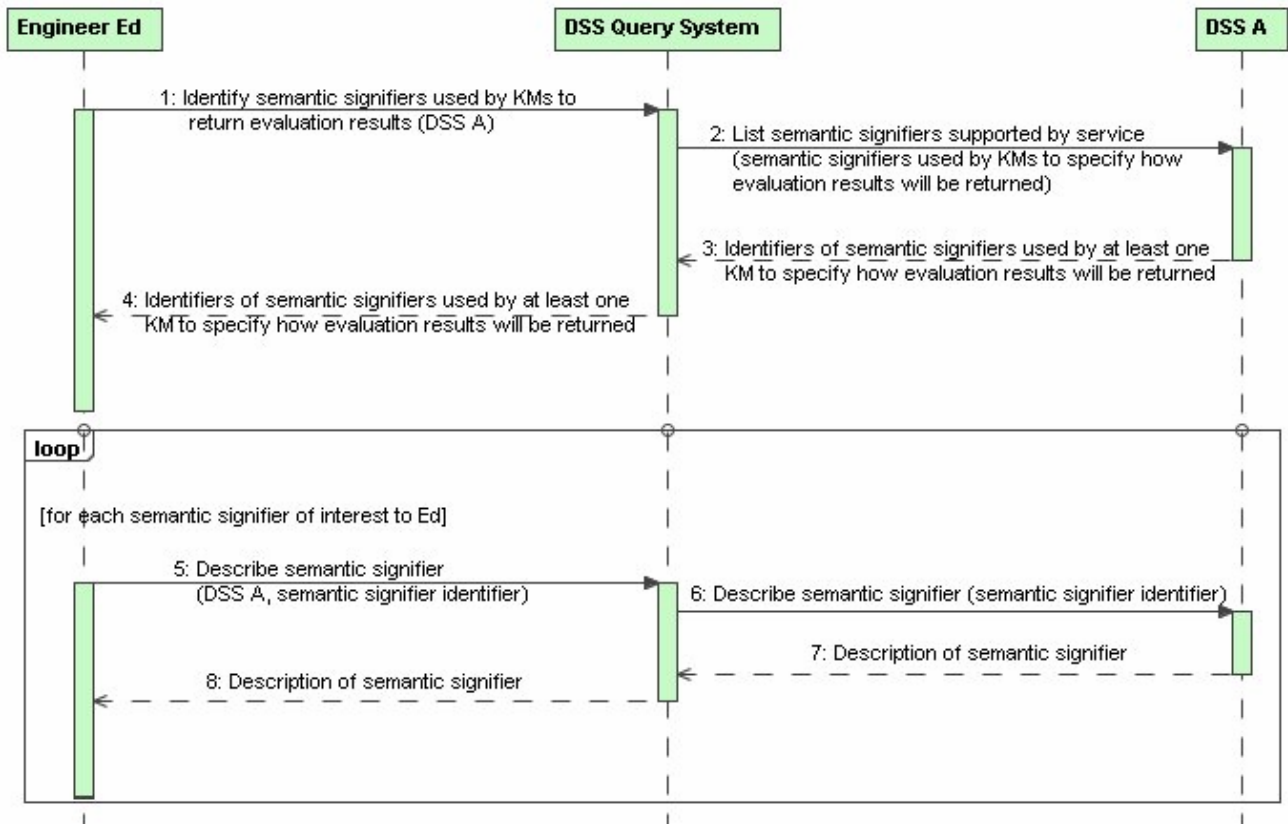


1122

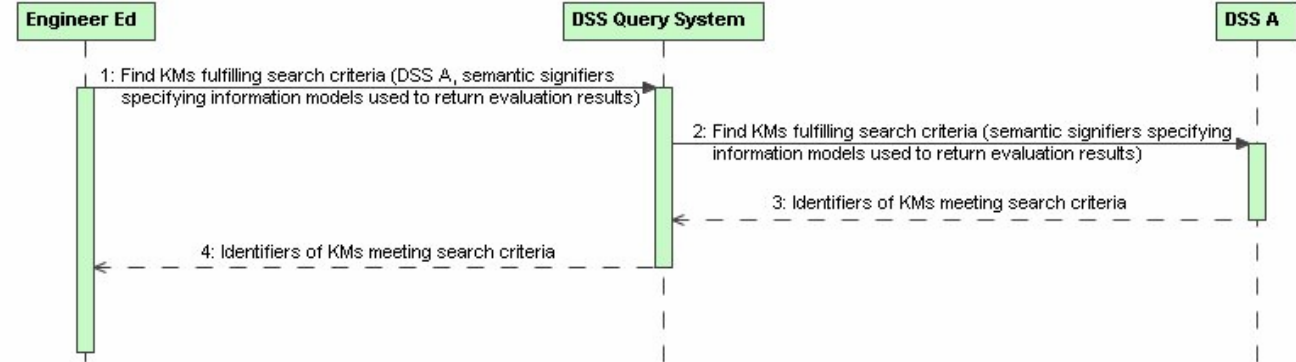
Question # 3: Which KMs possess the specified KM requirement(s), status(es), and/or KM trait(s)?



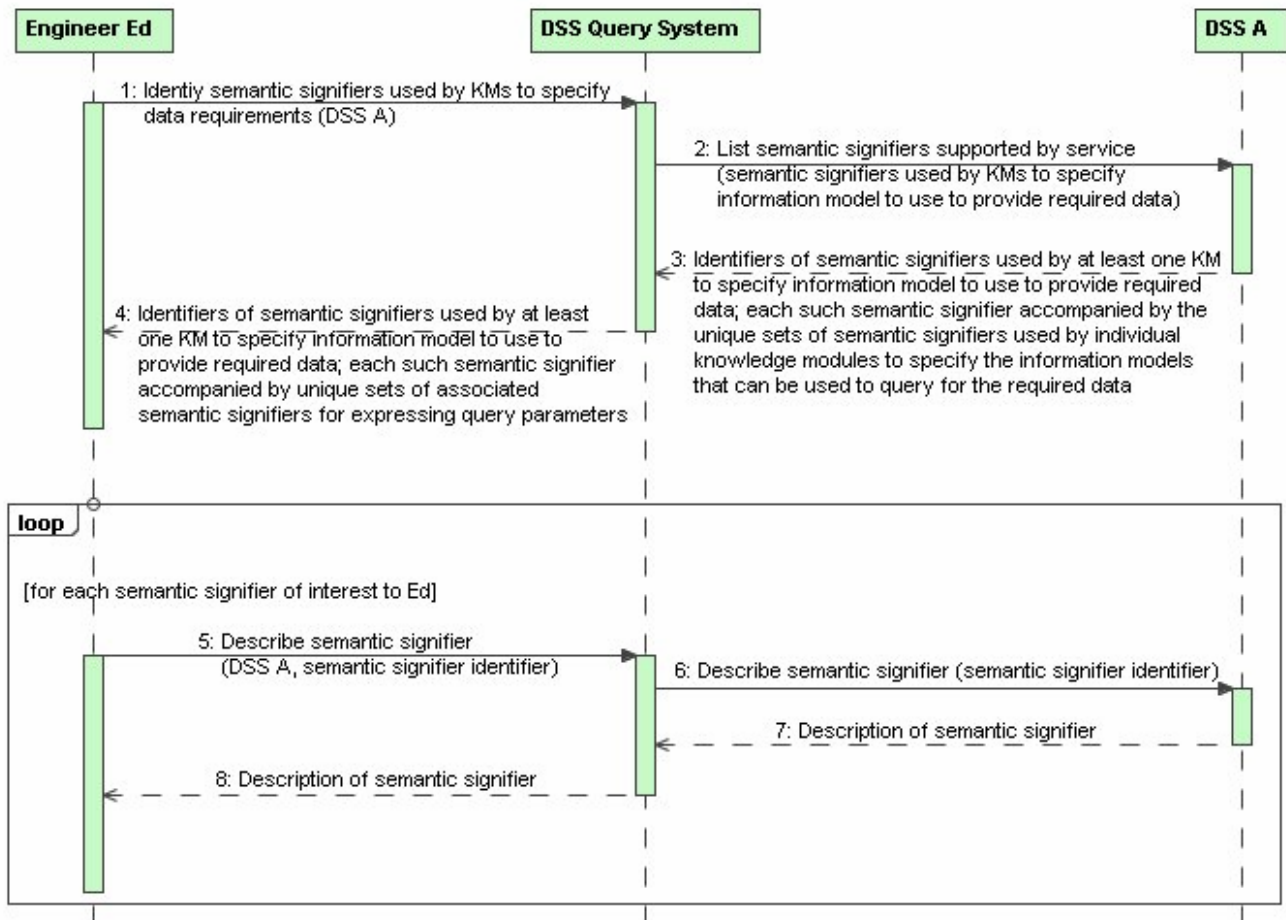
Question # 4: What semantic signifiers are used by the DSS's KMs to return evaluation results?



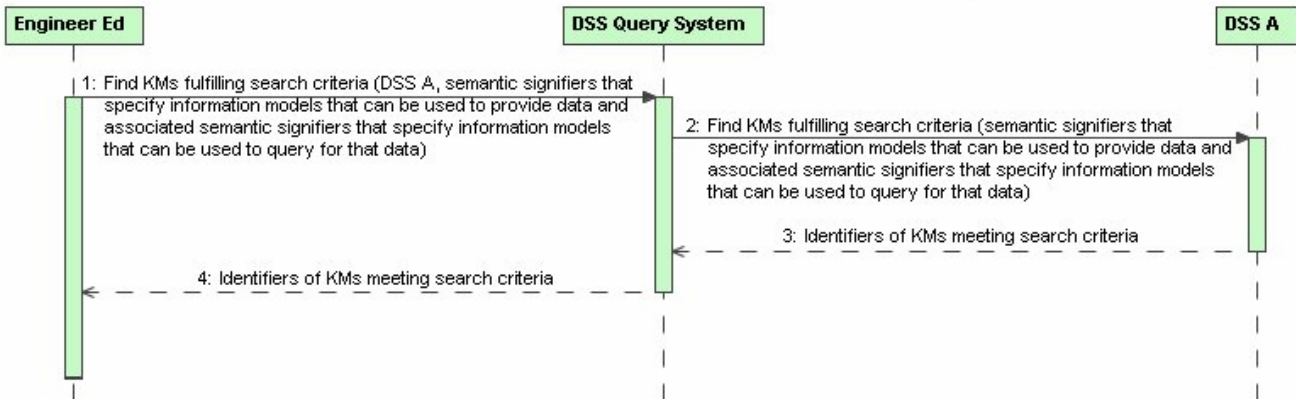
Question # 5: Which KMs return evaluation results using the specified semantic signifier(s)?



Question # 6: What semantic signifiers are used by the DSS's knowledge modules to specify their data requirements and the query parameters associated with those data requirements?

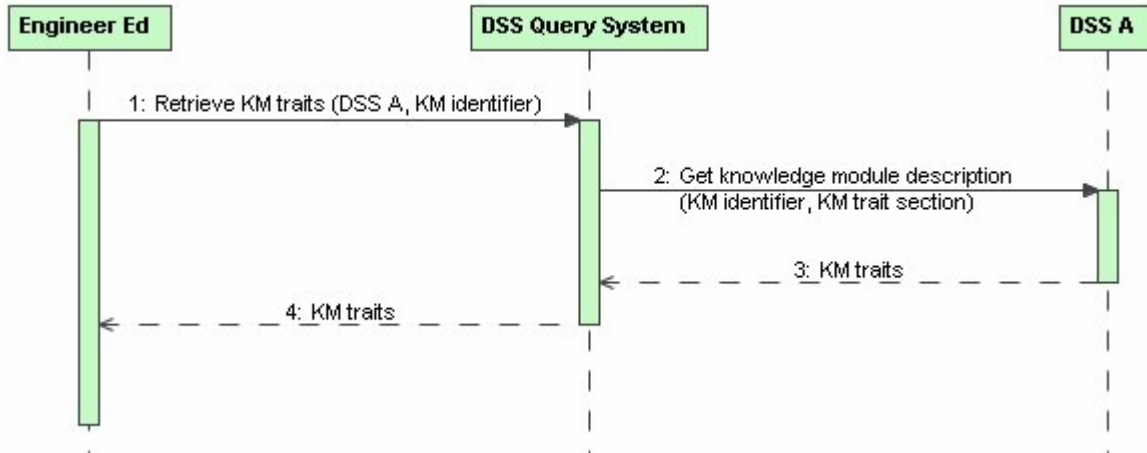


Question # 7: Which knowledge modules can be properly used given the data available to the client, as expressed by the semantic signifiers that specify the information models that can be used to provide data and the associated semantic signifiers that specify the information models that can be used to query for that data?



1132

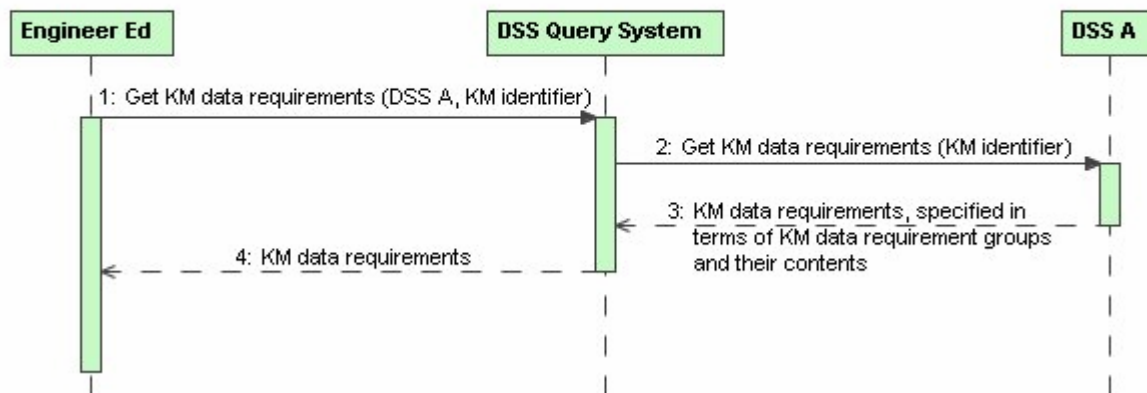
1133 7.1.1.3 Retrieval of Knowledge Module Traits



1134

1135 7.1.1.4 Retrieval of Knowledge Module Data Requirements

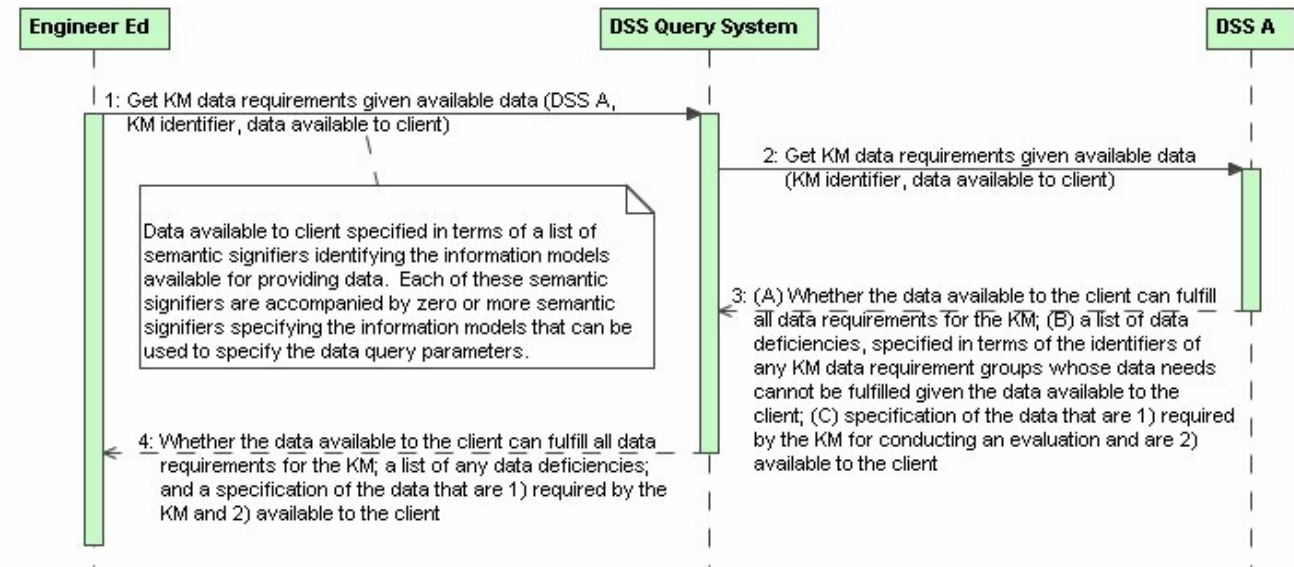
Option 1: Retrieve KM data requirements without regard to data available to client.



1136

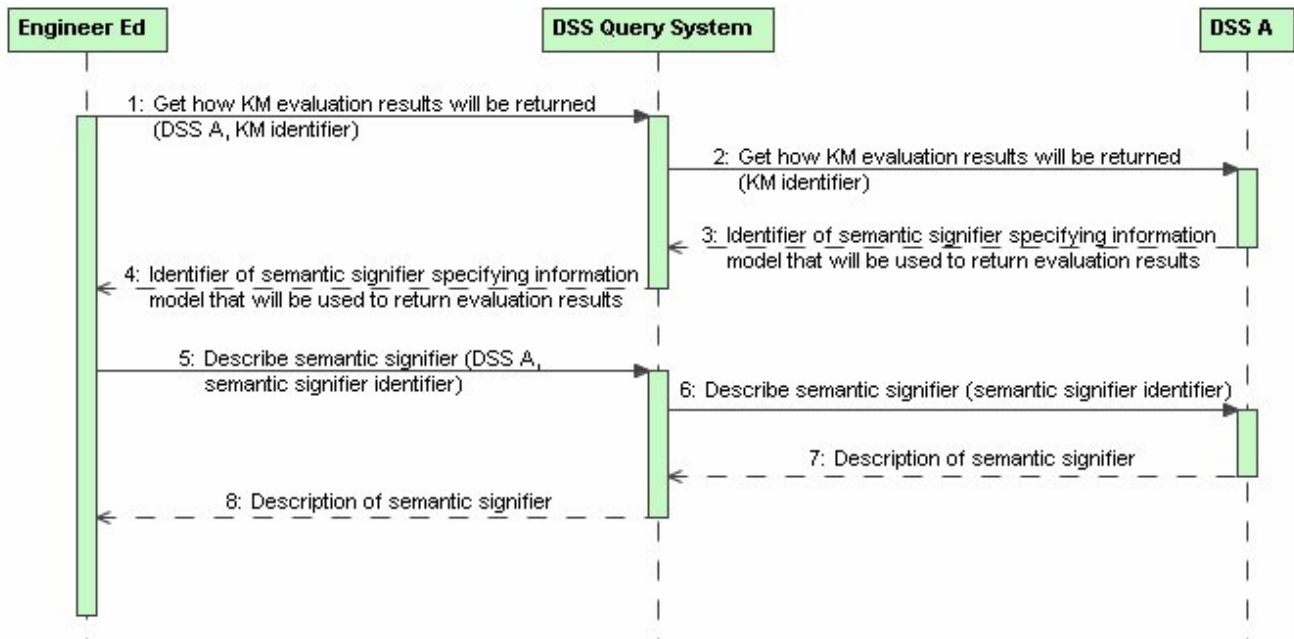
1137

Option 2: Retrieve KM data requirements given data available to client.



1138
1139

1140 7.1.1.5 Retrieval of How Evaluation Results will be Returned



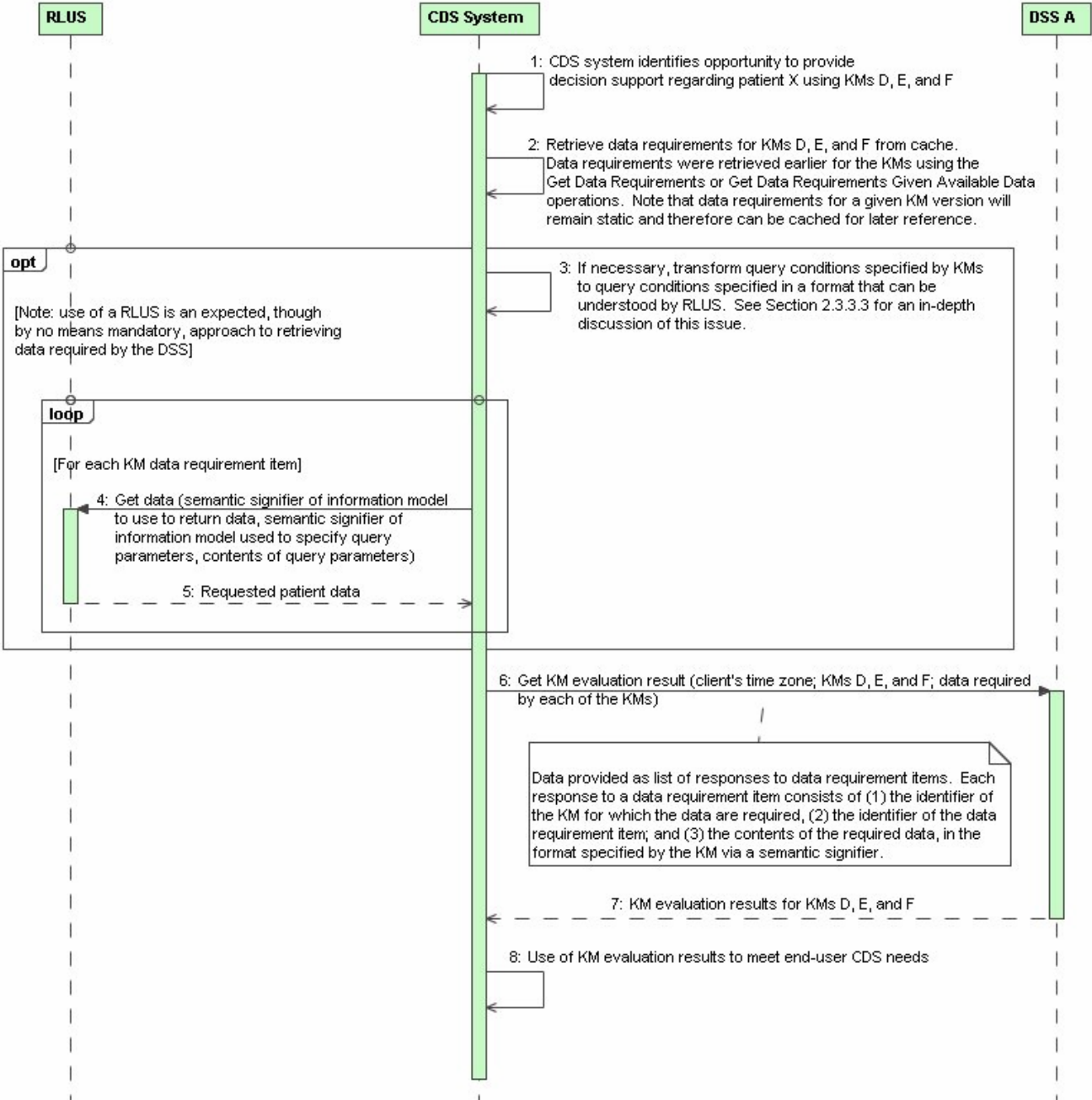
1141

1142

7.1.1.6 Evaluation of a Patient Using DSS Knowledge Modules and Use of Evaluation

1143

Results to Provide Context-Appropriate Clinical Decision Support



1144

1145

1146 **7.1.2 Specific Primary Scenarios**

1147 This section outlines specific scenarios that cover the use of a DSS by clients to meet their clinical
1148 decision support needs.

1149 **7.1.2.1 Provision of Chronic Disease Management and Preventive Care**
1150 **Recommendations to a Primary Care Clinician through an EHR System**

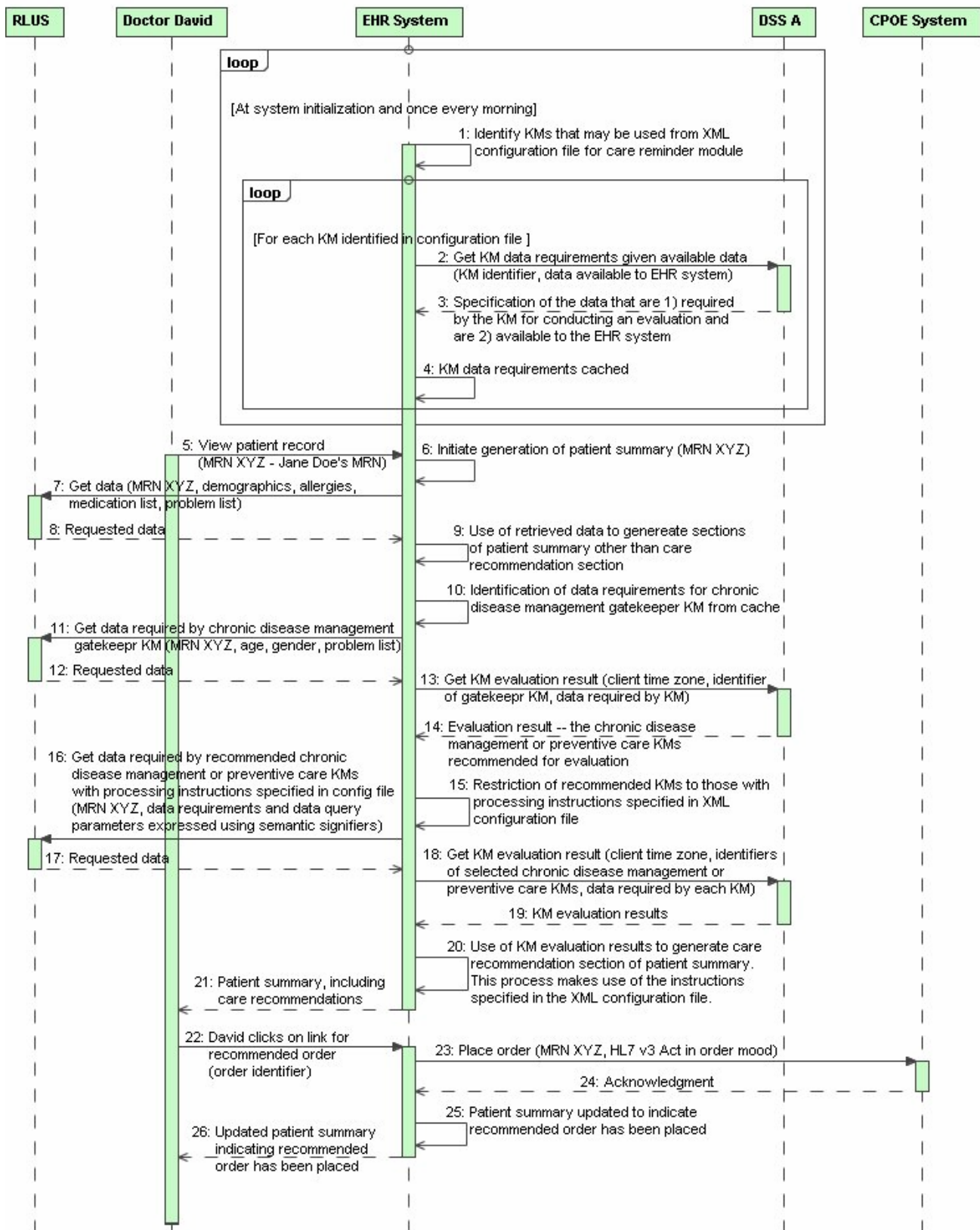
1151 **Scenario Details:** Jane checks into David's clinic. When David opens the patient's record in the EHR
1152 system, the EHR system initiates the generation of a patient summary, which includes the patient's
1153 problem list, allergies, medication list, and care recommendations.

1154 To generate the care recommendation section of the patient summary, the EHR system first asks DSS
1155 A to evaluate Jane using the DSS's "gatekeeper" knowledge module for chronic disease management
1156 and preventive care. The data requirements for this and all other knowledge modules used by the EHR
1157 system are retrieved from DSS A and cached at system initialization and also once every morning.

1158 Based on Jane's age, gender, and active problems, the gatekeeper knowledge module recommends that
1159 Jane be evaluated using the knowledge modules that evaluate for the patient's care needs with regard
1160 to colon cancer screening, breast cancer screening, cervical cancer screening, and twelve care issues
1161 related to the management of diabetes mellitus.

1162 The EHR system retrieves the data required by the knowledge modules from its clinical data repository
1163 via a RLUS interface. The EHR system then uses an XML-encoded configuration file that specifies
1164 how to populate the care reminder section of the patient summary using the evaluation results returned
1165 by DSS A. **Figure 6 in Appendix III** (Section 15) provides sample content for this configuration file,
1166 along with in-line comments. Of note, a sample of the knowledge modules referenced in this and other
1167 business scenarios are defined in detail in **Appendix II** (Section 14).

1168 Using the care recommendation provided to him by the EHR system, David reviews Jane's care needs
1169 during the encounter and decides to place several of the orders recommended by the EHR system. By
1170 clicking on the "order" link next to a care recommendation, David is able to place the appropriate order
1171 through the CPOE system.



1172

1173

1174 7.1.2.2 Provision of Medication Safety and Prescription Prior Authorization Decision
1175 Support to an Oncologist through an e-Prescribing System

1176 **Scenario Details:** John is seen by David at an oncology clinic. Towards the end of the visit, David
1177 begins to write prescriptions for John using an e-Prescribing system.

1178 When David enters a prescription, the e-Prescribing system uses the basic medication safety
1179 knowledge module hosted by DSS A to look for fundamental medication safety issues. The input and
1180 output requirements for this knowledge module have been standardized by HL7; the inputs consist of
1181 the patient's age, gender, height, weight, serum creatinine level, medication list, allergy list, problem
1182 list, and the medication proposed for prescription, and the output consists of standardized conclusions
1183 regarding drug-allergy contraindications, drug-drug interactions, and inappropriate dosing. Required
1184 data are retrieved from an EHR system through optimized queries performed through a direct database
1185 connection, and David is notified of any identified safety issues related to the proposed prescription.

1186 In addition to checking for medication safety issues, the e-Prescribing system has the proposed
1187 prescription evaluated by DSS B, which serves as the national repository of medication prior
1188 authorization rules within the United States of America. Each time David enters a prescription, the e-
1189 Prescribing system has the proposed medication and the patient's health insurance plan evaluated by a
1190 "gatekeeper" knowledge module that identifies whether the medication requires prior authorization
1191 and, if so, what knowledge module should be used to evaluate whether the prior authorization can be
1192 obtained.

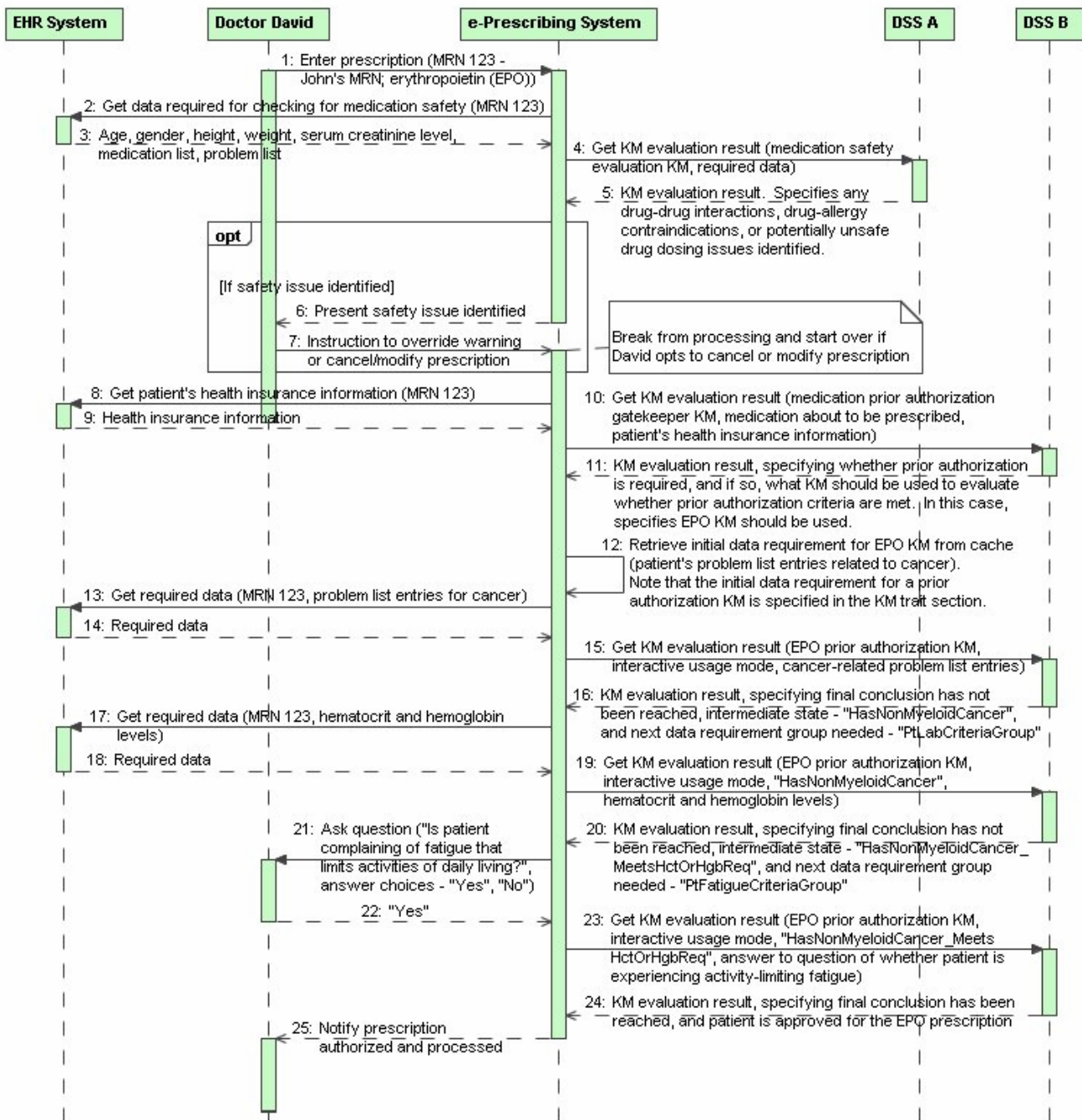
1193 For most of John's prescriptions, DSS B's gatekeeper knowledge module indicates that no prior
1194 authorization is required by the patient's insurer. However, for one of the prescriptions, erythropoietin
1195 (EPO), prior authorization is required by the patient's insurer, Insurance Company IC. Insurance
1196 Company IC's prior authorization rule for EPO stipulates that, for chemotherapy-induced anemia, 1)
1197 the patient must have a cancer other than myeloid or monocytic leukemia; 2) the patient's hematocrit
1198 must be < 30% or his hemoglobin must be < 11g/dL; and 4) the patient must be complaining of fatigue
1199 that limits an activity of daily living.

1200 The knowledge module for EPO authorization is designed so that all potentially required data can be
1201 provided to the knowledge module at once. In addition, the knowledge module is designed so that
1202 required data can be provided iteratively, and only for those data elements deemed to be necessary
1203 based on the data already provided. Also, in order to fully support client systems without access to
1204 electronic clinical data (e.g., lab results stored in a structured, electronic format), the EPO knowledge
1205 module specifies all data requirements both as structured data and as questions that can be answered by
1206 clinicians.

1207 The e-Prescribing system utilizes the EPO knowledge module in an interactive mode; the use of this
1208 interactive mode is specified as an input parameter submitted at the time of patient evaluation. This
1209 interaction between the e-Prescribing system and DSS B occurs as follows:

- 1210 1) The e-Prescribing system first provides the knowledge module with the patient's problem list,
1211 which is specified in the knowledge module trait section as the first piece of data required by the
1212 knowledge module when evaluating a patient in an interactive mode.
- 1213 2) Based on the patient's problem list, the knowledge module determines that the patient has cancer
1214 and that he does not have myeloid or monocytic leukemia. Therefore, the knowledge module
1215 concludes that John is potentially eligible for EPO therapy to ameliorate chemotherapy-induced
1216 anemia.

- 1217 3) To communicate its findings to the e-Prescribing system, the knowledge module returns an
1218 intermediate state variable that can be returned by the e-Prescribing system with the next
1219 evaluation request so that the patient's problem list does not need to be re-submitted. In addition,
1220 the knowledge module specifies in its evaluation result that the client should next provide data on
1221 the patient's hematocrit and hemoglobin levels.
- 1222 4) Steps 2 and 3 are repeated for providing data on the patient's relevant lab values. The data are
1223 retrieved from an associated EHR system, and the patient is again deemed to meet the prior
1224 authorization requirement.
- 1225 5) Finally, the knowledge module specifies that it now needs to know whether the patient is
1226 complaining of fatigue that limits an activity of daily living. Since this data element is not
1227 available from the EHR system, the e-Prescribing system asks David to provide the required
1228 information.
- 1229 6) When the e-Prescribing system submits the final evaluation request (including David's affirmative
1230 answer to the question of whether John is complaining of activity-limiting fatigue), the EPO
1231 knowledge module concludes that John is in fact eligible for EPO treatment.
- 1232 7) Consequently, DSS B notifies the e-Prescribing system that prior authorization has been approved
1233 for John's EPO treatment.
- 1234 Having obtained the prior authorization, David prescribes the EPO for John, and the e-Prescribing
1235 system notifies Insurance Company IC that the authorized EPO prescription will be dispensed in the
1236 near future.

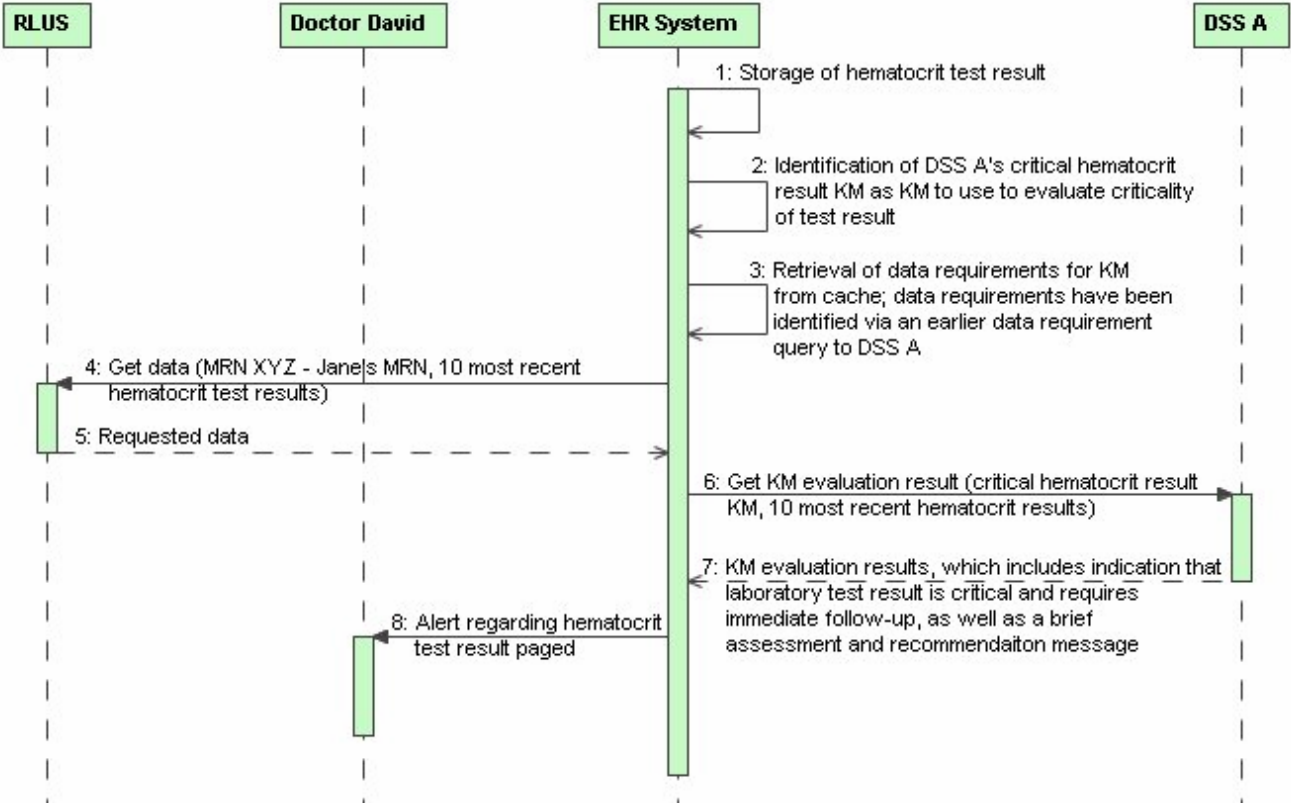


1238 7.1.2.3 Provision of Critical Laboratory Value Alert to a Physician on Call

1239 **Scenario Details:** David orders a CBC during rounds and proceeds with his other ward duties. When
1240 any test result is entered, the EHR system checks a configuration file that lists laboratory tests paired
1241 with the knowledge module that evaluates whether the test result requires immediate attention. The
1242 generation of this configuration file is facilitated by the fact that each knowledge module intended for
1243 this purpose is associated with a knowledge module trait that uses coded values to identify the specific
1244 test result(s) that are evaluated by that knowledge module.

1245 When storing the CBC result, the EHR system identifies that a knowledge module that checks for
1246 critical hematocrit values should be used to evaluate the hematocrit level. The EHR system identifies
1247 the data requirements for the hematocrit test as the 10 most recent hematocrit tests, and it obtains this
1248 data via its RLUS. Based on this data, DSS A is able to conclude that the hematocrit has been
1249 decreasing steadily and has now reached a sufficiently worrisome level. Given this evaluation result,
1250 the EHR system pages David with an alert regarding Jane’s hematocrit.

1251



1252

1253 **7.2 Supplemental Scenarios**

1254 **7.2.1 Generic Supplemental Scenarios**

1255 None defined.

1256 **7.2.2 Specific Supplemental Scenarios**

1257 **7.2.2.1 Provision of Context-Sensitive Reference Information to a Clinician through an** 1258 **EHR System**

1259 **Scenario Details:** The EHR system uses a knowledge module hosted by DSS C that fulfills a
1260 knowledge module requirement defined by the HL7 Clinical Decision Support Technical Committee
1261 for acting as a mediator for retrieving context-sensitive reference information. This type of knowledge
1262 module is referred to as a context-sensitive information retrieval knowledge module below, and a DSS
1263 hosting this type of knowledge module may be thought of as an “Infobutton manager.”

1264 To provide context-sensitive reference information to its clients, DSS C makes use of a knowledge
1265 module hosted by DSS D that fulfills a knowledge module requirement defined by the HL7 Clinical
1266 Decision Support Technical Committee for acting as a provider of context-sensitive reference
1267 information. This type of knowledge module is referred to as a context-sensitive information provider
1268 knowledge module below, and a DSS hosting this type of knowledge module may be thought of as an
1269 “e-Resource.”

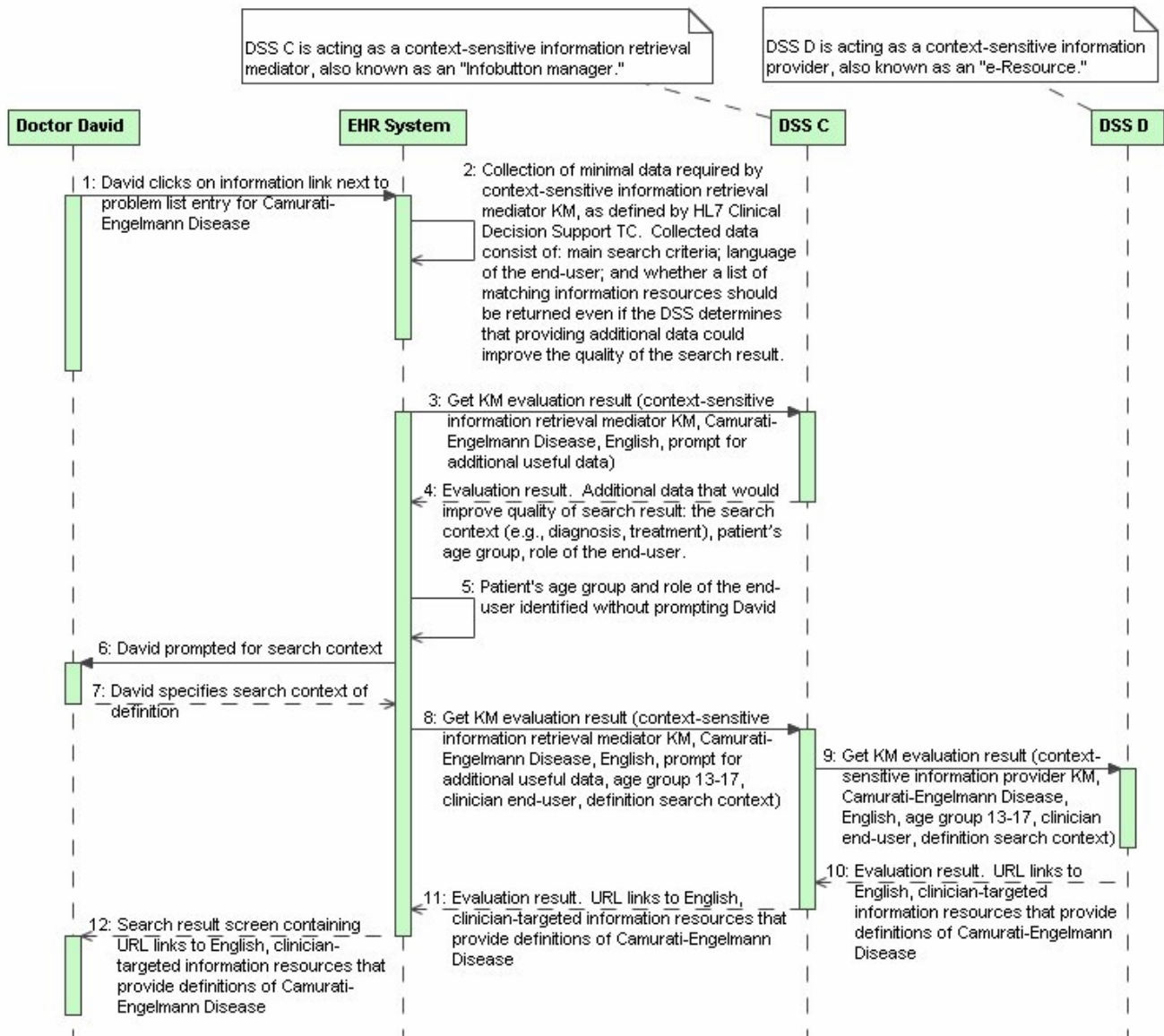
1270 A context-sensitive information retrieval mediator knowledge module requires a client to specify the
1271 main search criteria, the language of the end-user, and whether a list of matching information resources
1272 should be returned even if the DSS determines that providing additional data could improve the quality
1273 of the search result. If the DSS determines that additional data could improve the quality of the search
1274 result, and if the client has indicated that it wishes to be prompted for such data, the DSS will specify
1275 these additional data needs, which may include: the search subtopic (e.g., diagnosis, treatment), the
1276 patient’s age or age group, the patient’s gender, the role of the end-user (e.g., clinician), the reading
1277 level of the end-user, the task context of the end-user, the patient’s problem list, and/or the patient’s
1278 medication list. If the DSS determines that additional data are not required, or if the client has
1279 indicated that it does not wish to be prompted for additional data, the DSS will retrieve relevant
1280 information resources by utilizing a context-sensitive information provider knowledge module. These
1281 information resources will then be returned to the client.

1282 The data that can be required by a context-sensitive information provider knowledge module represent
1283 a proper subset of the data specified by HL7-I as allowable data requirements. These potential data
1284 requirements consist of: the main search criteria, the language of the end-user, the search subtopic
1285 (e.g., diagnosis, treatment), the patient’s age or age group, the patient’s gender, the role of the end-user
1286 (e.g., clinician), the reading level of the end-user, the care setting of the end-user, and/or the task
1287 context of the end-user. A client can identify which subset of query parameters are required by a
1288 knowledge module through the use of the Get Knowledge Module Data Requirements operation
1289 (Section 5.2.4). The knowledge module uses these data to retrieve and return relevant information
1290 resources to the client.

1291 In this particular business scenario, when David clicks on the information link next to Camurati-
1292 Engelmann Disease, the EHR system collects the minimal set of data required by DSS C’s context-
1293 sensitive information retrieval mediator knowledge module. This set of data includes the main search
1294 criteria (Camurati-Engelmann Disease) and the language of the end-user (English). Upon evaluating
1295 these data, DSS C notifies the EHR system that the quality of the search for relevant information

resources could be improved if the EHR system could provide additional data, regarding the search context, the patient's age group, and the role of the end-user. The EHR system identifies the patient's age group and role of the end-user without asking David, and then prompts David to identify the search context. When David selects disease definition as the context of the information need, the EHR system submits the initial, minimal set of data plus the newly collected data to DSS C. In turn, DSS C submits the data to the context-sensitive information provider knowledge module of DSS D, which returns URL links to relevant information resources.

The EHR system presents the URL links to David. By clicking on one of the search results, David is able to view the "Overview and definition" section of Camurati-Engelmann Disease in an online medical textbook.



1308 8 The Services Framework Functional Model

1309 The Services Framework Functional Model identifies common underlying enterprise infrastructure
1310 such as naming, directory, security, etc. that may be assumed and referenced by this Functional Model.

1311 Note that the Services Framework Functional Model is being developed in parallel with other service
1312 Functional Models; candidate functionality for the Framework should be submitted to the HSSP
1313 Infrastructure subgroup for evaluation.

1314

1315 9 Information Model and Semantic Binding Approach

1316 The following principles shall be followed for specifying the information model to be used by the
1317 services being specified in this Service Functional Model:

- 1318 • SFMs shall provide a conformance profile supporting HL7 content where relevant
- 1319 • We shall not preclude the use of non-HL7 content
- 1320 • SFMs will reuse to the maximum extent possible the content models as defined in other
1321 standards (for example, HL7 RMIMs, HL7 templates, OpenEHR archetypes, and Dutch
1322 National IT Institute for Healthcare Care Information Models)
- 1323 • Information content representations shall be represented in platform-agnostic formalisms (e.g.,
1324 UML)
- 1325 • SFMs may identify content at varying levels of granularity, depending upon the functions being
1326 specified. (For example, the Common Terminology Service will deal with different granularity
1327 of information than the Retrieve, Locate, and Update Service).
- 1328 • Conformance Profiles may be balloted or adopted after the release of the initial SFM to address
1329 specialized business needs (e.g., realm-specific profiles, domain-specific profiles)
- 1330 • Details about semantics specific to this SFM appear in other sections of this document

1331

1332 10 Recommendations for Technical RFP Issuance

1333 The OMG RFP issuance process involves the specification of mandatory requirements, optional
1334 requirements, and issues to be discussed by the RFP submitters. To facilitate and guide this RFP
1335 issuance process, this section highlights issues that should be addressed in the RFP, either as a
1336 requirement or as an issue to be discussed by RFP submitters.

1337 10.1 Management Interfaces

1338 As discussed in Section 2.3.1, DSS implementations may provide management interfaces that can be
1339 used by a DSS provider to manage and maintain knowledge modules and their associated meta-data.
1340 Such management interfaces are not specified in this functional model, however, as (1) a DSS provider
1341 may elect to manage and maintain knowledge modules and their associated meta-data without the use
1342 of such interfaces, and as (2) the availability and standardization of such management interfaces for
1343 use by DSS providers is not required to allow for interoperable use of DSSs by service clients.
1344 However, it is possible that the standardization of such management interfaces may be feasible and
1345 beneficial. For example, it may be useful to have a standard interface for verifying that all claims of
1346 conformance to knowledge module requirements are valid. Thus, it is recommended that the OMG
1347 requires technical RFP submitters to further consider and comment on the utility of specifying standard

1348 interfaces for performing management operations, including operations for validating claims of support
1349 for knowledge modules requirements.

1350 **10.2 Semantic Signifier Definitions**

1351 It is recommended that the OMG requires RFP submitters to specify how semantic signifier definitions
1352 are to be expressed for different types of semantic signifiers. Also, it is recommended that OMG
1353 requires RFP submitters to justify their approach to delivering computable definitions of semantic
1354 signifiers to clients. Note that, as discussed in Section 5.1.4, it may be acceptable for the definition of
1355 a semantic signifier to be obtained outside of the context of a DSS, for example through a common
1356 HSSP semantic signifier service.

1357 **10.3 Scalability**

1358 It is recommended that RFP submitters be required to comment on the scalability of their solutions. In
1359 particular, RFP submitters should be required to comment on how their solutions facilitate the
1360 provision of decision support when the scope of decision support content provided by a DSS becomes
1361 very large.

1362 **10.4 Knowledge Module Versioning**

1363 This SFM places several restrictions on knowledge module versioning. These restrictions include the
1364 following:

- 1365 - Knowledge modules must change versions if the data requirement specification or evaluation
1366 result specification changes (Section 2.3.4.3)
- 1367 - Knowledge modules must change versions following a modification to a knowledge module
1368 trait designated as requiring a knowledge module version change if modified (Section 2.3.4.3.2)

1369 It is recommended that further knowledge module versioning issues be considered in the RFP to ensure
1370 a consistent approach to the versioning and deprecation of knowledge modules across DSSs.

1371 **10.5 Constraints on Potential Values**

1372 The placement of constraints on potential values can facilitate interoperability. Thus, it is
1373 recommended that the RFP take steps to encourage or mandate the placement of constraints where
1374 appropriate. For example, data types may be limited to HL7 version 3 data types, and semantic
1375 signifier types may be limited to HL7 RMIMs, HL7 templates, OpenEHR archetypes, UML class
1376 diagrams, and XML schemas.

1377 ***10.5.1 Constraints on Vocabularies Used to Describe Knowledge Modules***

1378 This SFM does not restrict the vocabularies that may be used to specify keywords that describe a
1379 knowledge module (see Section 6.3.4.1). It is recommended that OMG RFP submitters be required to
1380 consider and address how the vocabularies used for this purpose should be constrained.

1381 ***10.5.2 Constraints on Potential Relationships between Knowledge Modules***

1382 It is recommended that OMG RFP submitters be required to define a value set that can be used to
1383 describe relationships between knowledge modules.

1384 **10.6 Adaptation of Service Capabilities**

1385 It is anticipated that adaptation of some of the service capabilities defined in Section 5 may be
1386 beneficial. For example, it may be more efficient to perform a single data requirement request
1387 encompassing multiple knowledge modules rather than to perform multiple data requirement requests

1388 that each encompasses a single knowledge module. Currently, only the latter operation is defined. It is
1389 recommended that such adaptation of service capabilities be allowed, as long as the RFP submitter
1390 provides a cogent justification for the adaptation.

1391 **10.7 Performance Optimization**

1392 In many contexts where clinical decision support must be provided, the speed with which the decision
1393 support can be generated and delivered is of critical importance. Thus, it is recommended that
1394 performance issues be considered when issuing the DSS RFP and when evaluating RFP submissions.

1395 **10.8 Approach to Leveraging HL7 Version 3 Domain Content**

1396 As discussed in Section 2.1.4, there is substantial HL7 version 3 content that could be used by a DSS.
1397 However, there are several factors that may make it difficult to use existing HL7 content without
1398 modification. For example, patient identifiers should generally not be communicated to a DSS (see
1399 Section 2.2.4), but most existing HL7 messages include patient identifiers as a core component of the
1400 message. Also, whereas a DSS will generally specify time-oriented query parameters in relative terms,
1401 existing HL7 query information models may specify time-oriented query parameters in absolute terms
1402 (see Section 2.3.3.3).

1403 Given these slight discrepancies in information models, it would be desirable if efficient procedures
1404 were available for (i) creating modified versions of existing HL7 information models for use by DSSs
1405 or for (ii) using existing HL7 information models “as is” in a manner that still meets the needs of DSSs
1406 (e.g., the population of patient identifiers with meaningless data). To address this important issue, it is
1407 recommended that RFP submitters be required to explore and comment on how to best leverage HL7
1408 version 3 domain content in DSS implementations.

1409

1410 **11 Assumptions**

1411 See Section 4.2 for a listing of assumptions.

1412

1413 **12 Glossary**

Term	Brief Description
CDA	Clinical Document Architecture
CDS	Clinical decision support; the provision of patient-specific assessments or recommendations to clinicians or other healthcare stakeholders to assist with clinical decision making
CDS system	A computer system that provides CDS
CEN	European Committee for Standardization
Client / client system	Unless otherwise specified, refers to a DSS client
CMET	Common Message Element Type
Conformance profile	A profile that consists of one or more functional profiles, one or more semantic profiles, and zero or more other constraints to be placed on a service
CPOE system	Computerized provider order entry system
DICOM	Digital Imaging and Communications in Medicine
DSS	Decision Support Service. A software system that provides clinical decision support capabilities as a service.
DSS client	Any external entity that interacts with a DSS to obtain its services. Example DSS

Term	Brief Description
	clients: DSS query system used by an engineer to find and explore knowledge modules at design time, operational CDS system that interacts with a DSS at run-time.
DSS provider	An entity that provides decision support services through a DSS interface
DSS query system	A system that can be used to query a DSS for information. Considered to be a type of DSS client.
Dutch National IT Institute for Healthcare Care Information Model	Specification of content (variables, relationships, vocabulary and coding, value sets), modeling of content, and technical specification in one document for clearly identified clinical items. At this stage expressed in HL7 v3 RMIM format, but work is ongoing to make it technology independent.
EHR system	Electronic health record system
e-Prescribing system	Electronic prescribing system
Functional profile	A profile that specifies a set of service operations that must be supported by a service claiming conformance to that profile
HIS	Hospital information system
HL7	Health Level 7
HSSP	Healthcare Services Specification Project
ISO	International Standards Organization
Knowledge module (KM)	The construct used by a DSS to organize and provide access to medical knowledge. See the computational meta-model of the service (Figure 4 in Section 2.3.4) for a computational definition of a knowledge module.
KM data requirement group	The primary organizing element for data required by a knowledge module. See Section 2.3.4.3.3.
KM data requirement item	A construct used to define data required by a knowledge module. See Section 2.3.4.3.4.
KM evaluation result	The conclusion returned by a DSS through the use of a knowledge module
KM requirement	A named requirement that must be fulfilled by a knowledge module claiming to fulfill the requirement. See Section 2.3.4.3.1.
KM trait	A named trait that can be used to describe or search for knowledge modules. See Section 2.3.4.3.2.
OMG	Object Management Group
Profile / Service profile	A named constraint placed on a service. See Section 2.3.2.
RIM	Reference Information Model
RMIM	Refined Message Information Model
RFP	Request for Proposal
RLUS	Retrieve, Locate, and Update Service
Scoping entity	Any entity that owns, defines, or otherwise scopes an information construct. See Section 2.3.4.1.
SDF	HSSP Service Development Framework. Main guide for generating this specification. Adaptation of the HL7 Development Framework (HDF) for the purpose of generating functional service specifications.
Semantic profile	A profile that specifies constraints on the information constructs that serve as payloads within service operations.
Semantic Signifier	Semantic Signifiers are identifiers of information constructs that specify the structure and meaning of data. See Section 2.3.3 for an extended description of semantic signifiers.

Term	Brief Description
SIG	Special Interest Group
SFM	Service Functional Model
TC	Technical Committee
UML	Unified Modeling Language

1414

13 Appendix I: Relevant Standards and Reference Content

The table below summarizes some of the standards and reference content relevant to this specification, as well as the relationship of these works to the DSS standard.

Table 8. Relevant standards and reference content, and their relationship to the DSS standard

Category	Standard or Reference Content	Relationship to the DSS Standard
Reference content – relevant prior work	SEBASTIAN	The DSS service framework is based on a Web service framework for clinical decision support known as SEBASTIAN (an acronym for <u>S</u> ystem for <u>E</u> vidence- <u>B</u> ased <u>A</u> dvice through <u>S</u> imultaneous <u>T</u> ransaction with an <u>I</u> ntelligent <u>A</u> gent across a <u>N</u> etwork). ¹⁰
Relevant standard – HL7	Version 3 Reference Information Model (RIM) and RIM-Derived Domain Content	HL7 version 3 content can be specified as service input or output parameters through the use of semantic signifiers (see Section 2.3.3). See Section 2.1.4 for an in-depth discussion of the use of HL7 v3 domain content by DSSs.
Relevant standard – HL7	HSSP Service Development Framework (SDF)	Main guide for generating this specification. Adaptation of the HL7 Development Framework (HDF) for the purpose of generating functional service specifications.
Relevant standard – HL7	Retrieve, Locate, and Update Service (RLUS)	An HSSP service specification for locating, accessing, and retrieving clinical data. The DSS is specified so that DSS data requirements can be fulfilled in a straightforward manner by using a RLUS. See Section 2.4.3 for a discussion of this topic.
Relevant standard – HL7	CDS TC GELLO standard	Medical knowledge encoded in GELLO could potentially be exposed to clients using a DSS interface.
Relevant standard – HL7	CDS TC initiative for guideline model convergence	A converged guideline model could be used by a DSS provider to implement knowledge modules.
Relevant standard – HL7	Proposed CDS TC standard for context-sensitive reference information retrieval (Infobutton standard)	The capabilities of this emerging standard could be exposed through a DSS interface. See the business scenario in Sections 3.3.2.1 and 7.2.2.1 for details.

¹⁰Kawamoto K and Lobach DF. Design, Implementation, Use, and Preliminary Evaluation of SEBASTIAN, a Standards-Based Web Service for Clinical Decision Support. *Proc AMIA Symp.* 2005;380-4.

14 Appendix II: Sample Decision Support Services (Non-Normative)

This section provides sample DSSs referenced in the business scenarios (Sections 3 and 7). Note that all content in this section is non-normative and provided only for illustrative purposes. Also, note that unless otherwise specified, all constructs requiring a version (e.g., knowledge module requirement, knowledge module trait) are associated with a version of 1.0.

14.1 Scoping Entities Supported by DSSs

Identifier	Name	Description
HL7-I	HL7 International	Health Level 7 (HL7) International
Vend-A	Vendor A	Vendor A
Vend-B	Vendor B	Vendor B
Vend-C	Vendor C	Vendor C
Vend-D	Vendor D	Vendor D

14.2 Knowledge Module Traits Used by DSSs to Describe KMs

Scoping Entity	Trait Identifier	Description	Data Type or Semantic Signifier	Change Requires KM Version Change
HL7-I	LastReviewDate	Date when KM was last reviewed for accuracy	HL7 V3 Point in Time	No
HL7-I	StewardOrganization	The organization acting as the steward of the KM	HL7 V3 Organization entity	No
HL7-I	KeywordListEnglishFreeText	A list of English free text keywords that characterize the KM. May be empty.	List of HL7 V3 Character Strings	No
HL7-I	KeywordListCodedValue	A list of keywords that characterize the KM, represented using coded values from one or more vocabularies. May be empty.	List of HL7 V3 Coded Values	No
HL7-I	Purpose	The purpose of a KM in English text (intended for a medical informaticist)	HL7 V3 Character String	No

Scoping Entity	Trait Identifier	Description	Data Type or Semantic Signifier	Change Requires KM Version Change
HL7-I	Explanation	An English text explanation of how the KM uses the required data to generate evaluation results (intended for a medical informaticist)	HL7 V3 Character String	No
HL7-I	AuthorList	A list of the KM's authors	List of HL7 V3 Person entities	No
HL7-I	CreationDate	Date KM was first created	HL7 V3 Point in Time	No
HL7-I	VersionHistory	Version history of KM	Semantic signifier for HL7 template expressing the version history of a document	No
HL7-I	ResultCodeDef	Specification of the meaning of result codes returned by a KM as part of an evaluation result	Semantic signifier for information model that contains a list of result codes that can be returned by a KM, along with a description of when those result codes will be returned	Yes
HL7-I	ResultParamDef	Specification of the meaning of result parameters returned by a KM as part of an evaluation result	Semantic signifier for information model that contains a list of result parameters that will be returned by a KM, along with a description of what will be provided as the parameter value	Yes
HL7-I	GuidelineShortEnglishDesc	English text describing the clinical guideline(s) underlying the KM, in 100 characters (including white space) or less (intended for a clinician)	HL7 V3 Character String	Yes
HL7-I	GuidelineLongEnglishDesc	English text describing the clinical guideline(s) underlying the KM, in 800 characters (including white space) or less (intended for a clinician)	HL7 V3 Character String	Yes
HL7-I	FirstDataReqGroupForInteractiveUse	The identifier of the first KM data requirement group to send to the DSS when using the KM in an interactive mode, in addition to the "AlwaysRequired" data requirement group	HL7 V3 Character String	Yes

Scoping Entity	Trait Identifier	Description	Data Type or Semantic Signifier	Change Requires KM Version Change
HL7-I	ContextSensitiveInfoProvider_AvailableContent	Specification of the information resources available through the KM. Can specify, for example, that English-language resources meant for clinicians as well as patients are available regarding common and rare genetic diseases.	Semantic signifier for information model, to be defined by HL7 Clinical Decision Support Technical Committee, that defines the information resources available through the KM.	Yes
Vend-A	EvokingActIdentifierList	The coded values identifying the acts which should lead to the KM being evoked. For a KM that evaluates whether a specific laboratory test result requires immediate attention, for example, this list should contain the code(s) identifying the laboratory test.	List of HL7 V3 Coded Values	Yes

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14.3 Knowledge Module Trait Criteria that can be Used to Query for KMs Based on Trait

Scoping Entity	Trait Identifier	Criterion Identifier	Description	Data Type
HL7-I	LastReviewDate	ReviewedOnOrAfter	Specifies that LastReviewDate must have been on or after the specified date	HL7 V3 Point in Time
HL7-I	LastReviewDate	ReviewedWithinLast XDays	Specifies that LastReviewDate must have occurred within specified number of days	HL7 V3 Integer Number
HL7-I	StewardOrganization	StewardOrganization Identifier	Specifies that steward organization must have the identifier specified	HL7 V3 Instance Identifier
HL7-I	StewardOrganization	StewardOrganization NameContains	Specifies that steward organization name must contain the string specified	HL7 V3 Character String
HL7-I	KeywordListEnglishFreeText	KeywordContains	Specifies that a keyword must contain the specified string	HL7 V3 Character String
HL7-I	KeywordListCodedValue	KeywordExists	Specifies that the specified code exists as a keyword	HL7 V3 Coded Value
HL7-I	KeywordListCodedValue	KeywordOrKeyword DescendantExists	Specifies that the specified code or a descendant concept exists as a keyword	HL7 V3 Coded Value
HL7-I	ContextSensitiveInfoProvider _AvailableContent	LanguageSupported	Specifies that content must be available in the specified language	HL7 V3 Coded Value
HL7-I	ContextSensitiveInfoProvider _AvailableContent	UserRoleSupported	Specifies that content must be available for the specified user role (e.g., clinician, patient)	HL7 V3 Coded Value
HL7-I	ContextSensitiveInfoProvider _AvailableContent	ContentTypeSupported	Specifies that content must be available for the specified content type (e.g., information on genetic diseases)	HL7 V3 Coded Value
Vend-A	EvokingActIdentifierList	EvokingActExists	Specifies that the specified evoking act exists	HL7 V3 Coded Value
Vend-A	EvokingActIdentifierList	EvokingActOrAct DescendantExists	Specifies that the specified evoking act or a descendant concept exists	HL7 V3 Coded Value

14.4 Profiles Supported by DSSs

Profile Type	Scoping Entity	Profile Identifier	Definition
Functional profile	HL7-I	DssFP_CoreFunctionality	Service supports all operations defined in this SFM, with the exception of the [Get Knowledge Module Evaluation Result as if it was the Specified Time] operation
Functional profile	HL7-I	DssFP_AdvancedTimeHandling	Service supports all operations defined in this SFM, including the [Get Knowledge Module Evaluation Result as if it was the Specified Time] operation
Semantic profile (KM requirement type)	HL7-I	DssSP_AllKmsSupport_CoreKmTraitReq	All KMs of the service fulfill the HL7-I KmReq_CoreKmTraitReq knowledge module requirement
Semantic profile (KM requirement type)	HL7-I	DssSP_SomeKmsSupport_CdmGateKeeperKm_and_CdmKm	Service required to offer: - At least one KM that supports the HL7-I KmReq_CdmGateKeeperKm knowledge module requirement - At least one KM that supports the HL7-I KmReq_CdmKm knowledge module requirement
Semantic profile (KM requirement type)	HL7-I	DssSP_SomeKmsSupport_ContextSensitiveInfoRetrievalMediatorKm	Service required to offer at least one KM that supports the HL7-I KmReq_ContextSensitiveInfoRetrievalMediatorKm knowledge module requirement
Semantic profile (KM requirement type)	HL7-I	DssSP_SomeKmsSupport_ContextSensitiveInfoProviderKm	Service required to offer at least one KM that supports the HL7-I KmReq_ContextSensitiveInfoProviderKm knowledge module requirement

1442 **14.5 Knowledge Module Requirements Supported by DSSs**

KM Requirement Type	Scoping Entity	Requirement Identifier	Definition
KM trait requirement	HL7-I	KmReq_CoreKmTraitReq	<p>KM supports the following KM traits:</p> <ul style="list-style-type: none"> - HL7-I LastReviewDate - HL7-I StewardOrganization - HL7-I KeywordListEnglishFreeText - HL7-I KeywordListCodedValue - HL7-I Purpose - HL7-I Explanation
KM evaluation result requirement	HL7-I	KmReq_CdmGateKeeperKm	<p>KM uses following information model to return evaluation result:</p> <pre> classDiagram class CDMGatekeeper["CDM Gatekeeper KM Evaluation Result"] class DSSKM["DSS KM"] { +scoping entity identifier : String +KM identifier : String +KM version : String } CDMGatekeeper --> "0..*" DSSKM : +Chronic disease management KM recommended for evaluation note for DSSKM "Recommended KMs fulfill the KmReq_CdmKm knowledge module requirement" </pre>
KM requirement aggregate	HL7-I	KmReq_CdmKm	<p>KM fulfills the following KM requirements:</p> <ul style="list-style-type: none"> - HL7-I KmReq_CdmKm_EvalResultDef - HL7-I KmReq_CdmKm_KmTraitDef
KM evaluation result requirement	HL7-I	KmReq_CdmKm_EvalResultDef	<p>KM uses following information model to return evaluation result:</p> <pre> classDiagram class CDMKMEval["CDM KM Evaluation Result"] { +result code : String } class ResultParameter["Result Parameter"] { +name : String +value : String } class HL7v3["HL7 v3 Act in Order Mood"] CDMKMEval --> "0..*" ResultParameter : +includes ResultParameter --> "0..*" HL7v3 : +recommends </pre>

KM Requirement Type	Scoping Entity	Requirement Identifier	Definition
KM trait requirement	HL7-I	KmReq_CdmKm_KmTraitDef	In addition to KM traits defined by HL7-I KmReq_CoreKmTraitReq, KM supports the following traits: - HL7-I ResultCodeDef - HL7-I ResultParamDef - HL7-I GuidelineShortEnglishDesc - HL7-I GuidelineLongEnglishDesc
KM requirement aggregate	HL7-I	KmReq_BasicMedSafetyKm	KM fulfills the following KM requirements: - HL7-I KmReq_BasicMedSafetyKm_EvalResultDef - HL7-I KmReq_BasicMedSafetyKm_DataReqSpecification
KM evaluation result requirement	HL7-I	KmReq_BasicMedSafetyKm_EvalResultDef	KM uses following information model to return evaluation result: <pre> classDiagram class BMSEKMER["Basic Medication Safety KM Evaluation Result"] class DAC["Drug-Allergy Contraindication"] class DASR["Dose Above or Below Safety Range"] class UDDI["Unsafe Drug-Drug Interaction"] BMSEKMER --> DAC : +proposed medication order has 0..* BMSEKMER --> DASR : +proposed medication order has 0..* BMSEKMER --> UDDI : +proposed medication order has 0..* class DAC { +allergen : Code +allergy reaction : Code +severity of contraindication : Code } class DASR { +dosing problem type : Code +max safe dose for patient : Physical Quantity +min safe dose for patient : Physical Quantity +percent above max safe dose : Number +percent below min safe dose : Number } class UDDI { +interacting drug : Code +interaction : Code +severity of interaction : Code } </pre>
KM data meta-requirement	HL7-I	KmReq_BasicMedSafetyKm_DataReqSpecification	KM data requirements consist of a single data requirement group with the following data requirement items: - medication that is about to be prescribed for a patient - patient's age - patient's gender - patient's weight - patient's height - patient's most recent serum creatinine level - patient's medication list - patient's allergy list - patient's problem list

KM Requirement Type	Scoping Entity	Requirement Identifier	Definition
KM requirement aggregate	HL7-I	KmReq_InteractiveKm	KM fulfills the following KM requirements: - HL7-I KmReq_InteractiveKm_EvalResultDef - HL7-I KmReq_InteractiveKm_DataReqSpecification - HL7-I KmReq_InteractiveKm_KmTraitDef
KM evaluation result requirement	HL7-I	KmReq_InteractiveKm_EvalResultDef	KM uses following information model to return evaluation result: <div data-bbox="1129 477 1486 602"> <p>Interactive KM Evaluation Result</p> <p>+final conclusion reached : Boolean +intermediate state reached : String +next data requirement group id : String</p> </div> <div data-bbox="1142 651 1476 760"> <p>Note: information model may be extended as needed and still be compliant with this information model</p> </div> <div data-bbox="1530 477 1875 773"> <p>- Final conclusion reached -- always true if in non-interactive mode; if in interactive mode, may be true or false - Intermediate state reached -- only provided if in interactive mode. Clients should provide this value as an input when next asking for an evaluation using the KM. - Next data requirement group id -- only provided if in interactive mode. Client should provide the specified data requirement as an input when next asking for an evaluation using the KM</p> </div>
KM trait requirement	HL7-I	KmReq_InteractiveKm_DataReqSpecification	KM data requirements must include: - a data requirement group which specifies (a) whether the KM should be utilized in an interactive mode and (b) the intermediate state reached by a prior use of the KM in interactive mode - other data requirement groups as appropriate
KM trait requirement	HL7-I	KmReq_InteractiveKm_KmTraitDef	In addition to KM traits defined by HL7-I KmReq_CoreKmTraitReq, KM supports the following traits: - HL7-I FirstDataReqGroupForInteractiveUse
KM requirement aggregate	Vend-B	KmReq_MedPriorAuthKm	KM fulfills the following KM requirements: - HL7-I KmReq_InteractiveKm - Vend-B KmReq_MedPriorAuthKm_EvalResultDef

KM Requirement Type	Scoping Entity	Requirement Identifier	Definition
KM evaluation result requirement	Vend-B	KmReq_MedPriorAuthKm_EvalResultDef	<p>KM uses following information model to return evaluation result:</p> <div> <p>Medication Prior Authorization KM Evaluation Result</p> <p>+final conclusion reached : Boolean +intermediate state reached : String +next data requirement group id : String +prior authorization approved : Boolean</p> </div> <div> <p>- Final conclusion reached -- always true if in non-interactive mode; if in interactive mode, may be true or false - Intermediate state reached -- only provided if in interactive mode. Clients should provide this value as an input when next asking for an evaluation using the KM. - Next data requirement group id -- only provided if in interactive mode. Client should provide the specified data requirement as an input when next asking for an evaluation using the KM - Prior authorization approved -- will be null if final conclusion reached == false. Otherwise, returns true or false.</p> </div>
KM requirement aggregate	Vend-A	KmReq_CriticalLabTestKm	<p>KM fulfills the following KM requirements:</p> <ul style="list-style-type: none"> - Vend-A KmReq_CriticalLabTestKm_EvalResultDef - Vend-A KmReq_CriticalLabTestKm_TraitDef
KM evaluation result requirement	Vend-A	KmReq_CriticalLabTestKm_EvalResultDef	<p>KM uses following information model to return evaluation result:</p> <div> <p>Critical Laboratory Test KM Evaluation Result</p> <p>+labTestCriticality : Code +assessment : String +recommendation : String</p> </div> <p>0..* +recommended action</p> <div> <p>HL7 v3 Act in Order Mood</p> </div>
KM trait requirement	Vend-A	KmReq_CriticalLabTestKm_TraitDef	<p>In addition to KM traits defined by HL7-I KmReq_CoreKmTraitReq, KM supports the following traits:</p> <ul style="list-style-type: none"> - Vend-A EvokingActIdentifierList

KM Requirement Type	Scoping Entity	Requirement Identifier	Definition
KM requirement aggregate	HL7-I	KmReq_ContextSensitiveInfoRetrievalMediatorKm	<p>KM fulfills the following KM requirements:</p> <ul style="list-style-type: none"> - HL7-I KmReq_ContextSensitiveInfoRetrievalMediatorKm_EvalResultDef - HL7-I KmReq_ContextSensitiveInfoRetrievalMediatorKm_DataReqSpecification
KM evaluation result requirement	HL7-I	KmReq_ContextSensitiveInfoRetrievalMediatorKm_EvalResultDef	<p>KM uses following information model to return evaluation result:</p> <pre> classDiagram class ContextSensitiveInfoRetrievalMediatorKMEvalResult["Context-Sensitive Information Retrieval Mediator KM Evaluation Result"] class ResultIfMoreInformationRequired["Result if More Information Required"] class ResultIfMoreInformationNotRequired["Result if More Information Not Required"] class RequiredData["Required Data"] class InformationResource["Information Resource"] class PointerToInformationResource["Pointer to Information Resource"] ContextSensitiveInfoRetrievalMediatorKMEvalResult < -- ResultIfMoreInformationRequired ContextSensitiveInfoRetrievalMediatorKMEvalResult < -- ResultIfMoreInformationNotRequired ResultIfMoreInformationRequired --> "1..*" RequiredData : +requires ResultIfMoreInformationNotRequired --> "0..*" InformationResource : +contains InformationResource --> "" : +resource type : Code, +resource contents : type specific contents ResultIfMoreInformationNotRequired --> "0..*" PointerToInformationResource : +contains PointerToInformationResource --> "" : +pointer type : Code, +pointer contents : type specific contents </pre> <p>The diagram illustrates the information model for the evaluation result. It features a base class, Context-Sensitive Information Retrieval Mediator KM Evaluation Result, which is specialized by two classes: Result if More Information Required and Result if More Information Not Required. The Result if More Information Required class is associated with Required Data (containing a data requirement group identifier : String) via a +requires relationship with a multiplicity of 1..*. The Result if More Information Not Required class is associated with Information Resource (containing +resource type : Code and +resource contents : type specific contents) via a +contains relationship with a multiplicity of 0..*. Additionally, the Result if More Information Not Required class is associated with Pointer to Information Resource (containing +pointer type : Code and +pointer contents : type specific contents) via a +contains relationship with a multiplicity of 0..*. A note indicates that the Pointer to Information Resource can be, for example, a URL.</p>

KM Requirement Type	Scoping Entity	Requirement Identifier	Definition
KM data meta-requirement	HL7-I	KmReq_ContextSensitiveInfoRetrievalMediatorKm_DataReqSpecification	<p>KM data requirements consist of a primary data requirement group containing data requirement items for query parameters that are always required, as well as other data requirement groups for query parameters that may be required in some cases to improve the quality of the search for information resources. These data requirement items are defined in terms of information models generated by the HL7 Clinical Decision Support Technical Committee for the purposes of context-sensitive information retrieval.</p> <p>The query parameter data that are always required include:</p> <ul style="list-style-type: none"> - the main search criteria - the language of the end-user - whether a list of matching information resources should be returned even if the DSS determines that providing additional data could improve the quality of the search result <p>The query parameter data that may be required in some cases to improve the quality of the search for information resources include:</p> <ul style="list-style-type: none"> - the search subtopic (e.g., diagnosis, treatment) - patient's age - patient's age group - patient's gender - the role of the end-user (e.g., clinician) - the reading level of the end-user - the care setting of the end-user - the task context of the end-user - patient's problem list - patient's medication list
KM requirement aggregate	HL7-I	KmReq_ContextSensitiveInfoProviderKm	<p>KM fulfills the following KM requirements:</p> <ul style="list-style-type: none"> - HL7-I KmReq_ContextSensitiveInfoProviderKm_EvalResultDef - HL7-I KmReq_ContextSensitiveInfoProviderKm_DataReqSpecification - HL7-I KmReq_ContextSensitiveInfoProviderKm_TraitDef

KM Requirement Type	Scoping Entity	Requirement Identifier	Definition
KM evaluation result requirement	HL7-I	KmReq_ContextSensitiveInfoProviderKm_EvalResultDef	<p>KM uses following information model to return evaluation result:</p> <pre> classDiagram class ContextSensitiveInfoProviderKM_EvalResultDef { } class InformationResource { +resource type : Code +resource contents : type specific contents } class PointerToInformationResource { +pointer type : Code +pointer contents : type specific contents } ContextSensitiveInfoProviderKM_EvalResultDef "0..*" --> "0..*" InformationResource : +contains ContextSensitiveInfoProviderKM_EvalResultDef "0..*" --> "0..*" PointerToInformationResource : +contains </pre>
KM data requirement superset requirement	HL7-I	KmReq_ContextSensitiveInfoProviderKm_DataReqSupersetSpecification	<p>KM data requirements are to consist of a single data requirement group.</p> <p>The single data requirement group may contain one or more query parameters. These data requirement items are defined in terms of information models generated by the HL7 Clinical Decision Support Technical Committee for the purposes of context-sensitive information retrieval.</p> <p>The query parameters that may be required include:</p> <ul style="list-style-type: none"> - the main search criteria - the language of the end-user - the search subtopic (e.g., diagnosis, treatment) - patient's age - patient's age group - patient's gender - the role of the end-user (e.g., clinician) - the reading level of the end-user - the care setting of the end-user - the task context of the end-user <p>Note that a KM should only require a query parameter if it will make use of it to differentiate between information resources returned to the client.</p>
KM trait requirement	HL7-I	KmReq_ContextSensitiveInfoProviderKm_TraitDef	<p>In addition to KM traits defined by HL7-I KmReq_CoreKmTraitReq, KM supports the following traits:</p> <ul style="list-style-type: none"> - HL7-I ContextSensitiveInfoProvider_AvailableContent

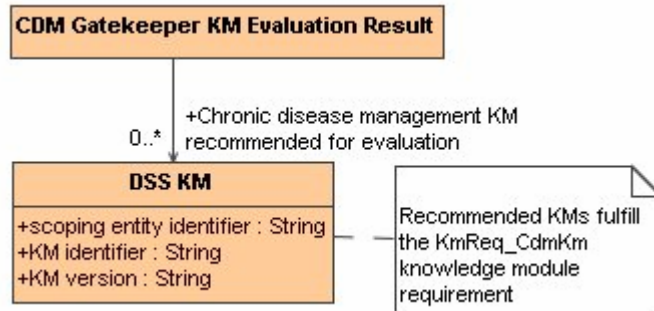
- 1443 **14.6 Vendor A DSS (DSS A)**
- 1444 ***14.6.1 Profiles Supported by Vendor A DSS***
- 1445 • Functional profiles supported
- 1446 ○ HL7-I DssFP_CoreFunctionality
- 1447 • Semantic profiles supported
- 1448 ○ HL7-I DssSP_AllKmsSupport_CoreKmTraitReq
- 1449 ○ HL7-I DssSP_SomeKmsSupport_CdmGateKeeperKm_and_CdmKm

1450 **14.6.2 Sample Knowledge Modules Hosted by DSS A**

1451 **14.6.2.1 Chronic Disease Management Gatekeeper Knowledge Module**

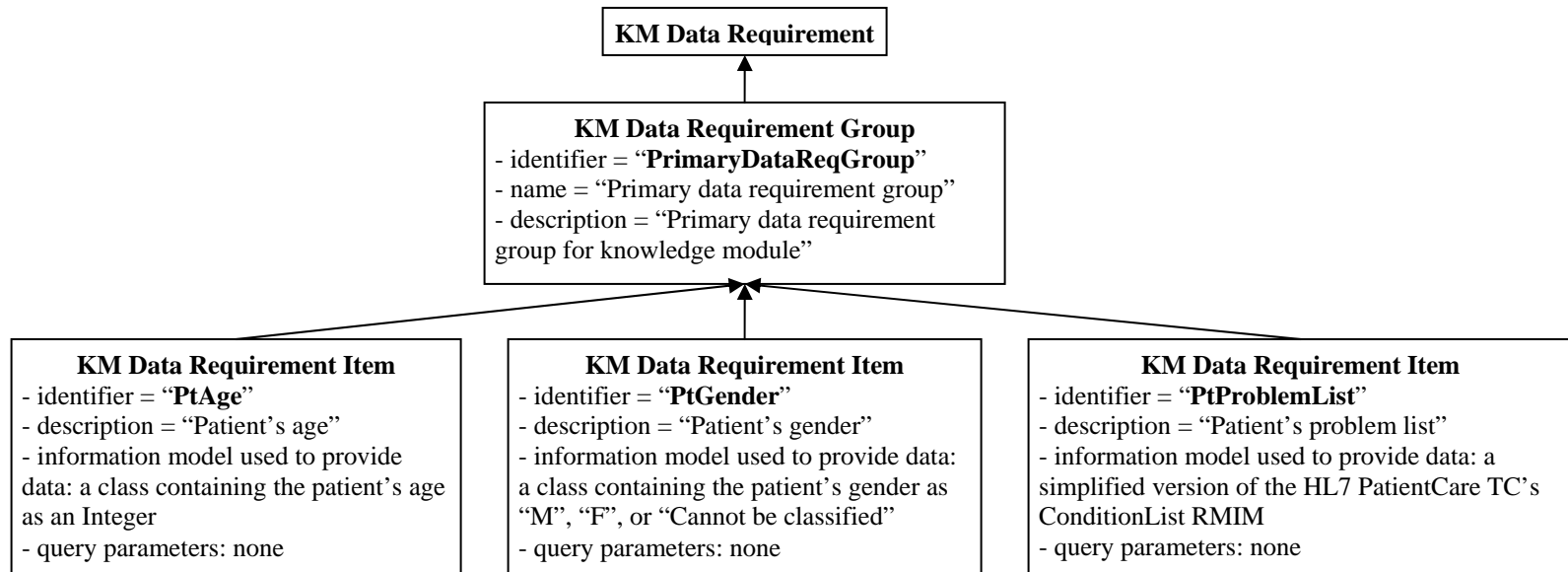
- 1452 - KM identifying information:
 - 1453 ○ Scoping entity identifier: Vend-A
 - 1454 ○ KM identifier: cdm_gatekeeper
 - 1455 ○ Version: 1.00
 - 1456 ○ Status: In Production
- 1457 - KM requirements fulfilled by KM:
 - 1458 ○ HL7-I KmReq_CoreKmTraitReq
 - 1459 ○ HL7-I KmReq_CdmGateKeeperKm
- 1460 - KM traits:
 - 1461 ○ StewardOrganization → Vendor A
 - 1462 ○ AuthorList → Kensaku Kawamoto, Ph.D.
 - 1463 ○ CreationDate → 2006-06-19T02:27:00
 - 1464 ○ LastReviewDate → 2006-06-19T02:27:00
 - 1465 ○ VersionHistory → 2006-06-19T02:27:00 – initial creation by Kensaku Kawamoto, Ph.D.
 - 1466 ○ KeywordListEnglishFreeText → “disease management”, “chronic care”, “preventive care”, “health maintenance”, “diabetes mellitus”, “colonoscopy”, etc.
 - 1467 ○ KeywordListCodedValue → above concepts represented as coded values
 - 1468 ○ Purpose → “The purpose of this knowledge module is to identify the chronic disease management/preventive care knowledge modules recommended for evaluating the patient under consideration. The intent is to avoid wasting computational resources through the evaluation of patients using knowledge modules that clearly do not apply, such as the evaluation of a male patient with a knowledge module that evaluates for the need of a Pap test, or the evaluation of a patient without diabetes with a knowledge module that evaluates whether a patient with diabetes is in need of a hemoglobin A1c test.”
 - 1473 ○ Explanation → “This knowledge module takes the patient’s age, gender, and problem list to identify those knowledge modules related to chronic disease management or preventive care that are recommended for evaluating the patient under consideration.”

1477 - KM evaluation result information model:



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- KM data requirements:



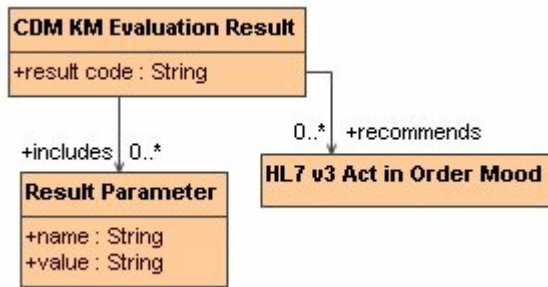
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1483 14.6.2.2 Sample Chronic Disease Management Knowledge Module

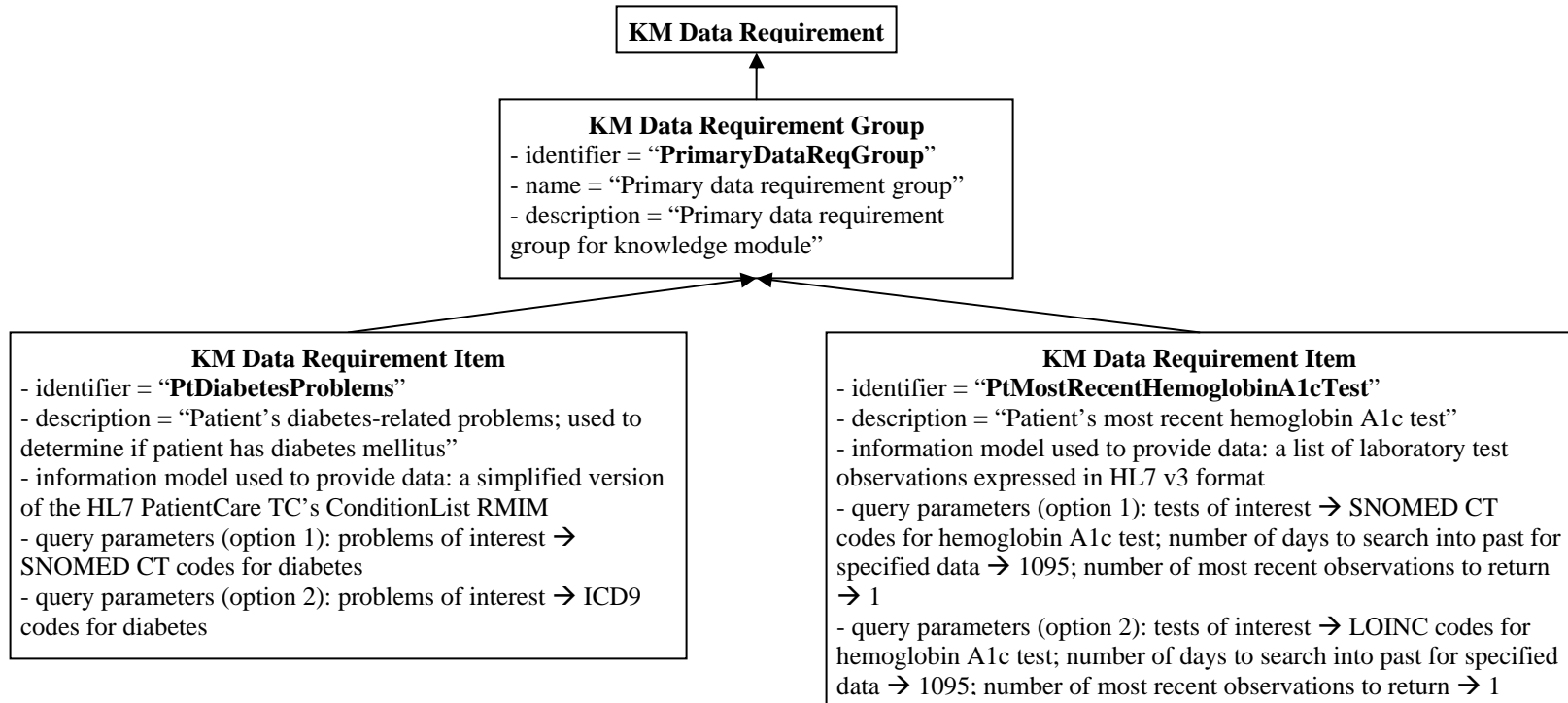
- 1484 - KM identifying information:
 - 1485 ○ Scoping entity identifier: Vend-A
 - 1486 ○ KM identifier: diabetes_need_for_hgbA1c_test
 - 1487 ○ Version: 1.00
 - 1488 ○ Status: In Production
- 1489 - KM requirements fulfilled by KM:
 - 1490 ○ HL7-I KmReq_CoreKmTraitReq
 - 1491 ○ HL7-I KmReq_CdmKm
 - 1492 ■ HL7-I KmReq_CdmKm_EvalResultDef
 - 1493 ■ HL7-I KmReq_CdmKm_KmTraitDef
- 1494 - KM traits:
 - 1495 ○ StewardOrganization → Vendor A
 - 1496 ○ AuthorList → Kensaku Kawamoto, Ph.D.
 - 1497 ○ CreationDate → 2006-06-19T03:24:00
 - 1498 ○ LastReviewDate → 2006-06-19T03:24:00
 - 1499 ○ VersionHistory → 2006-06-19T03:24:00 – initial creation by Kensaku Kawamoto, Ph.D.
 - 1500 ○ KeywordListEnglishFreeText → “diabetes mellitus”, “hemoglobin A1c”, “glycated hemoglobin”
 - 1501 ○ KeywordListCodedValue → above concepts represented as coded values
 - 1502 ○ Purpose → “The purpose of this knowledge module is to evaluate whether a patient appears to have diabetes and is in need of
 - 1503 a hemoglobin A1c test, which is recommended every 3 months if the patient’s last hemoglobin A1c test was $\geq 7\%$, or every
 - 1504 6 months otherwise.”
 - 1505 ○ Explanation → “This knowledge module first identifies whether a patient appears to have diabetes mellitus by looking to see
 - 1506 if the patient has a problem list entry indicative of the disease. If the patient is deemed to have diabetes, the patient’s most
 - 1507 recent hemoglobin A1c test is identified and it is determined whether a patient is due for or not due for the test.”
 - 1508 ○ GuidelineShortEnglishDesc → “Monitor q3 months if last hemoglobin A1c $\geq 7\%$, q6 months otherwise”
 - 1509 ○ GuidelineLongEnglishDesc → “A patient with diabetes mellitus should have his or her hemoglobin A1c level tested every 3
 - 1510 months if the patient’s last hemoglobin A1c level was greater than or equal to 7%, and every 6 months otherwise. This
 - 1511 recommendation is based on the following clinical trials:”
 - 1512 ○ ResultCodeDef →
 - 1513 ■ “001” – “Patient does not appear to have diabetes mellitus”
 - 1514 ■ “002” – “Patient does appear to have diabetes mellitus but is not due for a hemoglobin A1c test”
 - 1515 ■ “003” – “Patient does appear to have diabetes mellitus and to be due for a hemoglobin A1c test”

- ResultParamDef →
 - “last_done_date_time” → Date test was last done in ISO format. “N/A” returned if patient deemed to not have diabetes or last test done >= 3 years ago. Note that this knowledge module asks for the most recent hemoglobin A1c test from the past 3 years; tests that are older are not provided to the DSS and therefore cannot be used to populate evaluation result parameters.
 - “time_since_last_done” → Time elapsed since last done, as “[Years]||[Months]||[Days]”, e.g., “1|3|14” to indicate 1 year, 3 months, and 14 days. Returns “>3|0|0” if last test done >=3 years ago. “N/A” returned if patient deemed to not have diabetes.
 - “last_done_value” → Value of last test, e.g., “7.3”. “N/A” returned if patient deemed to not have diabetes or last test done >= 3 years ago.
 - “last_done_value_unit” → Unit associated with value of last test. In this case, will be “%”. “N/A” returned if patient deemed to not have diabetes or last test done >= 3 years ago.

- KM evaluation result information model:



1532 - KM data requirements:

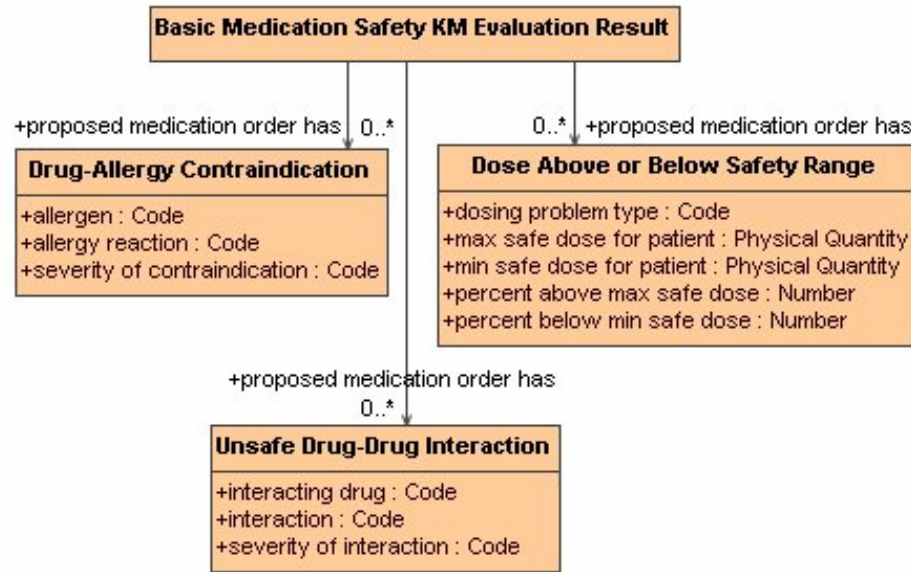


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- 1534 14.6.2.3 Basic Medication Safety Decision Support Knowledge Module
- 1535 - KM identifying information:
- 1536 o Scoping entity identifier: Vend-A
- 1537 o KM identifier: basic_medication_safety_evaluation
- 1538 o Version: 1.00
- 1539 o Status: In Production
- 1540 - KM requirements fulfilled by KM:
- 1541 o HL7-I KmReq_CoreKmTraitReq
- 1542 o KmReq_BasicMedSafetyKm
- 1543 ▪ KmReq_BasicMedSafetyKm_EvalResultDef
- 1544 ▪ KmReq_BasicMedSafetyKm_DataReqSpecification
- 1545 - KM traits:
- 1546 o StewardOrganization → Vendor A
- 1547 o AuthorList → Kensaku Kawamoto, Ph.D.
- 1548 o CreationDate → 2006-06-21T10:35:00
- 1549 o LastReviewDate → 2006-06-21T10:35:00
- 1550 o VersionHistory → 2006-06-21T10:35:00 – initial creation by Kensaku Kawamoto, Ph.D.
- 1551 o KeywordListEnglishFreeText → “medication safety”, “drug-drug interactions”, “drug-allergy contraindications”,
- 1552 “medication dosing”, “renal dosing”, etc.
- 1553 o KeywordListCodedValue → above concepts represented as coded values
- 1554 o Purpose → “The purpose of this knowledge module is to provide basic decision support related to medication safety.
- 1555 Specifically, clinical decision support is provided with regard to drug-allergy contraindications, drug-drug interactions, and
- 1556 potentially unsafe medication dosing.”
- 1557 o Explanation → “This knowledge module takes the patient’s age, gender, height, weight, serum creatinine level, medication
- 1558 list, allergy list, problem list, and proposed medication. The knowledge module then identifies whether there are any
- 1559 potential safety issues that would arise from the prescription of the proposed medication.”

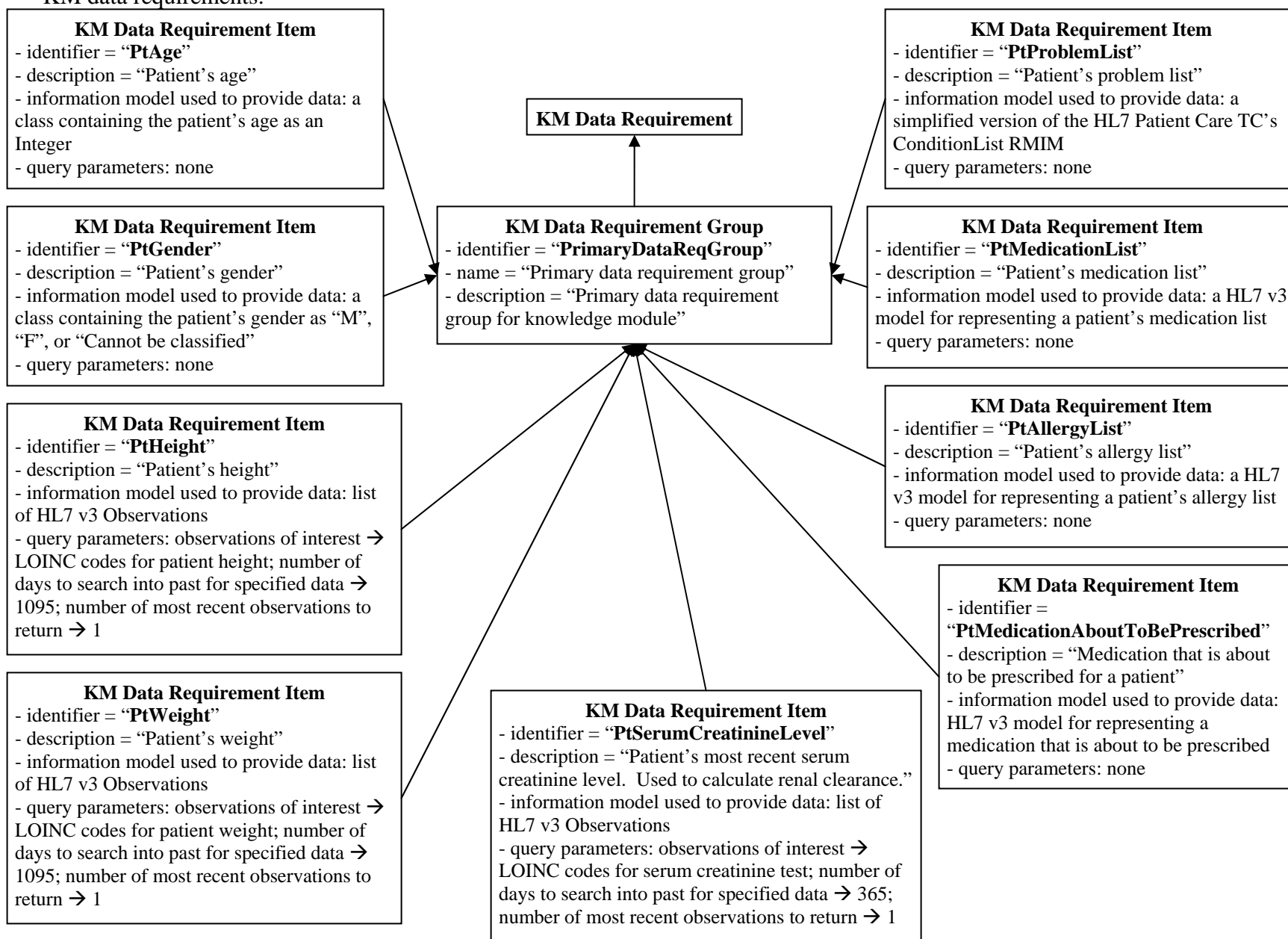
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- KM evaluation result information model:



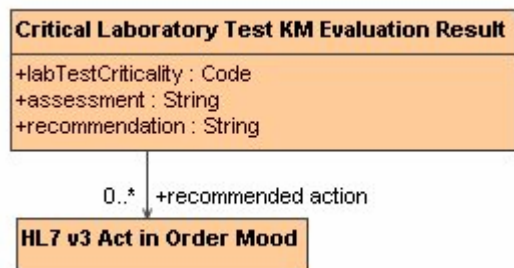
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- KM data requirements:

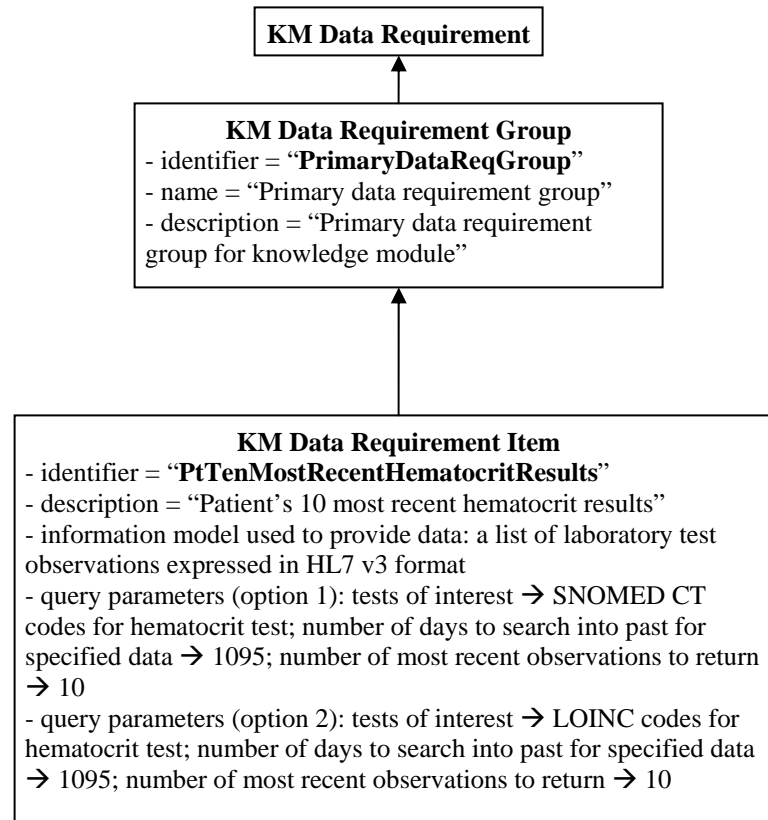


14.6.2.4 Sample Critical Laboratory Test Result Knowledge Module

- KM identifying information:
 - o Scoping entity identifier: Vend-A
 - o KM identifier: critical_hematocrit_result
 - o Version: 1.00
 - o Status: In Production
- KM requirements fulfilled by KM:
 - o HL7-I KmReq_CoreKmTraitReq
 - o Vend-A KmReq_CriticalLabTestKm
 - Vend-A KmReq_CriticalLabTestKm_EvalResultDef
 - Vend-A KmReq_CriticalLabTestKm_TraitDef
- KM traits:
 - o StewardOrganization → Vendor A
 - o AuthorList → Kensaku Kawamoto, Ph.D.
 - o CreationDate → 2006-06-22T017:40:00
 - o LastReviewDate → 2006-06-22T017:40:00
 - o VersionHistory → 2006-06-22T017:40:00 – initial creation by Kensaku Kawamoto, Ph.D.
 - o KeywordListEnglishFreeText → “critical laboratory result”, “hematocrit”
 - o KeywordListCodedValue → above concepts represented as coded values
 - o Purpose → “The purpose of this knowledge module is to evaluate whether the patient’s most recent hematocrit result is critical in nature and requires immediate follow-up.”
 - o Explanation → “This knowledge module evaluates the patient’s ten most recent hematocrit test results. Based on these results, it determines whether the most recent hematocrit level is sufficiently worrisome as to warrant immediate follow-up. This determination is made by considering both the value of the most recent hematocrit level and the trending among the previous hematocrit levels on record.”
 - o EvokingActIdentifierList → contains LOINC and SNOMED CT codes for the hematocrit test
- KM evaluation result information model:



1593 - KM data requirements:



1594

1595 **14.7 Vendor B DSS (DSS B)**

1596 **14.7.1 Profiles Supported by Vendor B DSS**

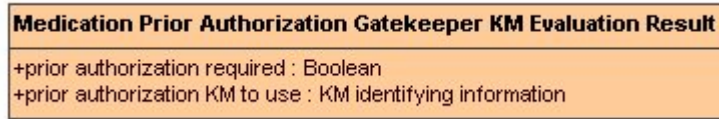
- 1597 • Functional profiles supported
 - 1598 ○ HL7-I DssFP_CoreFunctionality
- 1599 • Semantic profiles supported
 - 1600 ○ HL7-I DssSP_AllKmsSupport_CoreKmTraitReq

1601 **14.7.2 Sample Knowledge Modules Hosted by DSS B**

1602 14.7.2.1 Medication Prior Authorization Gatekeeper Knowledge Module

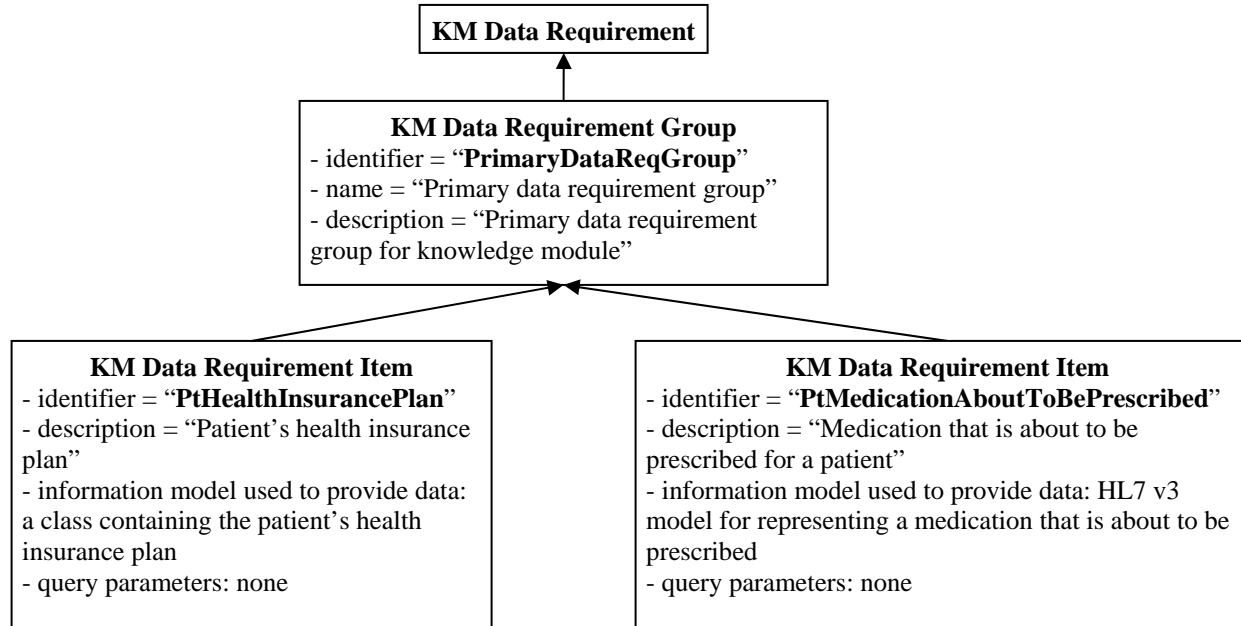
- 1603 - KM identifying information:
 - 1604 ○ Scoping entity identifier: Vend-B
 - 1605 ○ KM identifier: med_prior_auth_gatekeeper
 - 1606 ○ Version: 1.00
 - 1607 ○ Status: In Production
- 1608 - KM requirements fulfilled by KM:
 - 1609 ○ HL7-I KmReq_CoreKmTraitReq
- 1610 - KM traits:
 - 1611 ○ StewardOrganization → Vendor B
 - 1612 ○ AuthorList → Kensaku Kawamoto, Ph.D.
 - 1613 ○ CreationDate → 2006-06-22T08:00:00
 - 1614 ○ LastReviewDate → 2006-06-22T08:00:00
 - 1615 ○ VersionHistory → 2006-06-22T08:00:00 – initial creation by Kensaku Kawamoto, Ph.D.
 - 1616 ○ KeywordListEnglishFreeText → “medication prior authorization”
 - 1617 ○ KeywordListCodedValue → above concepts represented as coded values
 - 1618 ○ Purpose → “The purpose of this knowledge module is to identify whether prior authorization should be sought given a
 - 1619 patient’s health insurance plan and the medication about to be prescribed. If prior authorization is required, this knowledge
 - 1620 module specifies which prior authorization knowledge module should be used to determine if prior authorization conditions
 - 1621 are met.”
 - 1622 ○ Explanation → “This knowledge module takes the patient’s health insurance plan and the medication about to be prescribed
 - 1623 in order to determine whether prior authorization is required and, if so, which knowledge module should be used to evaluate
 - 1624 whether the prior authorization criteria are met.”

1625 - KM evaluation result information model:



1626
1627
1628

- KM data requirements:



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1630

1631 14.7.2.2 Sample Medication Prior Authorization Knowledge Module

1632 - KM identifying information:

1633 o Scoping entity identifier: Vend-B

1634 o KM identifier: erythropoietin_prior_authorization_insurance_company_ic

1635 o Version: 1.00

1636 o Status: In Production

1637 - KM requirements fulfilled by KM:

1638 o HL7-I KmReq_CoreKmTraitReq

1639 o HL7-I KmReq_InteractiveKm

1640 ▪ HL7-I KmReq_InteractiveKm_EvalResultDef

1641 ▪ HL7-I KmReq_InteractiveKm_DataReqSpecification

1642 ▪ HL7-I FirstDataReqGroupForInteractiveUse

1643 o Vend-B KmReq_MedPriorAuthKm

1644 ▪ HL7-I KmReq_InteractiveKm

1645 ▪ Vend-B KmReq_MedPriorAuthKm_EvalResultDef

1646 - KM traits:

1647 o StewardOrganization → Vendor B

1648 o AuthorList → Kensaku Kawamoto, Ph.D.

1649 o CreationDate → 2006-06-21T10:35:00

1650 o LastReviewDate → 2006-06-21T10:35:00

1651 o VersionHistory → 2006-06-21T10:35:00 – initial creation by Kensaku Kawamoto, Ph.D.

1652 o KeywordListEnglishFreeText → “medication prior authorization”, “erythropoietin”

1653 o KeywordListCodedValue → above concepts represented as coded values

1654 o Purpose → “The purpose of this knowledge module is to determine whether the patient meets prior authorization criteria for

1655 an erythropoietin prescription.”

1656 o Explanation → “This knowledge module identifies whether the patient meets prior authorization criteria for an erythropoietin

1657 prescription. To check if the patient meets the requirements for chemotherapy-induced anemia, this knowledge module

1658 checks for the following requirements: 1) the patient must have a cancer other than myeloid or monocytic leukemia; 2) the

1659 patient’s hematocrit must be < 30% or his hemoglobin must be < 11g/dL; and 4) the patient must be complaining of fatigue

1660 that limits an activity of daily living.”

1661 o FirstDataReqGroupForInteractiveUse → “PtProblemCriteriaGroup”

1662

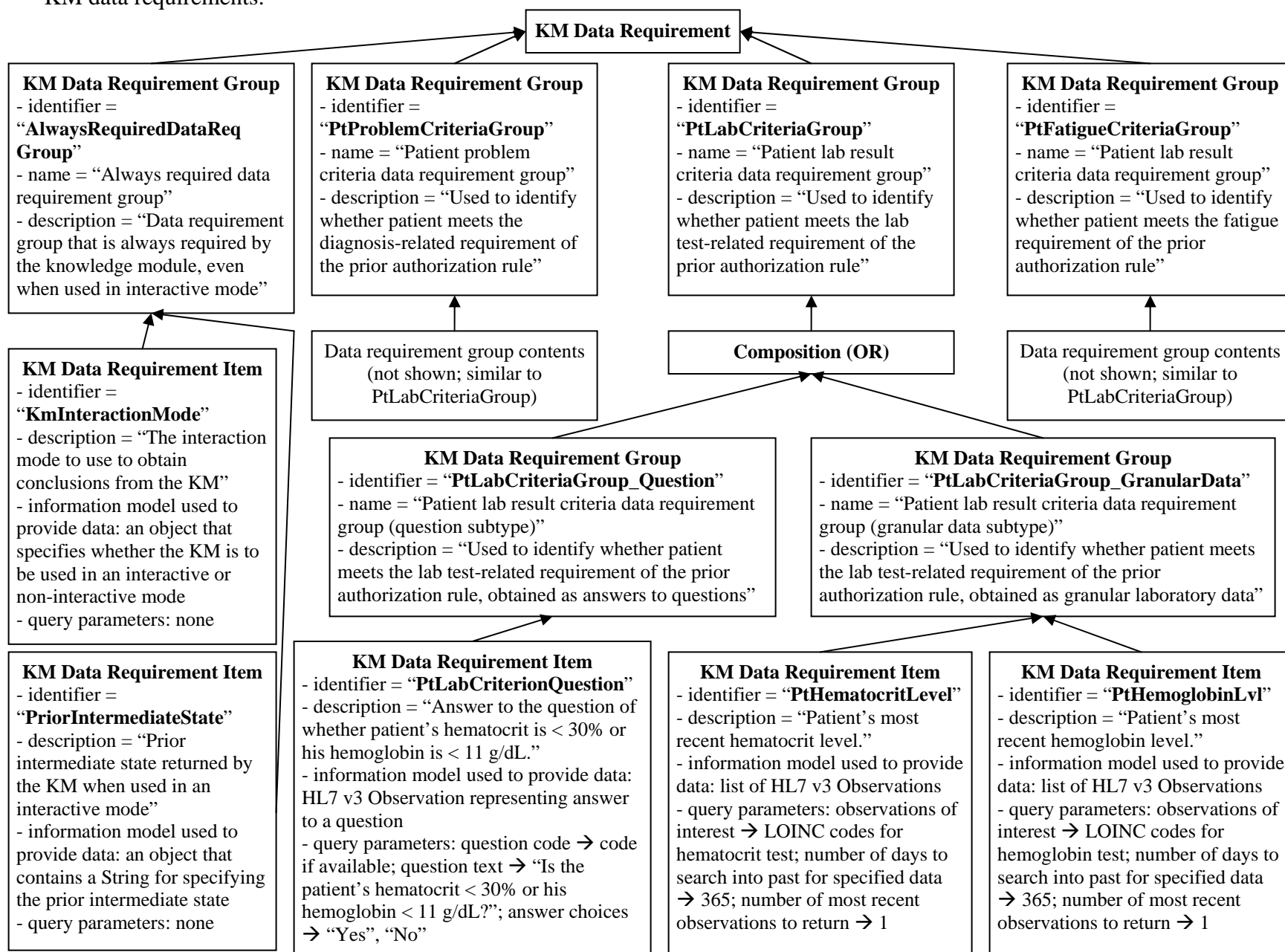
○ KM evaluation result information model:

Medication Prior Authorization KM Evaluation Result
+final conclusion reached : Boolean
+intermediate state reached : String
+next data requirement group id : String
+prior authorization approved : Boolean

- Final conclusion reached -- always true if in non-interactive mode; if in interactive mode, may be true or false
- Intermediate state reached -- only provided if in interactive mode. Clients should provide this value as an input when next asking for an evaluation using the KM.
- Next data requirement group id -- only provided if in interactive mode. Client should provide the specified data requirement as an input when next asking for an evaluation using the KM
- Prior authorization approved -- will be null if final conclusion reached == false. Otherwise, returns true or false.

1663

- KM data requirements:



- 1666 **14.8 Vendor C DSS (DSS C)**
- 1667 ***14.8.1 Profiles Supported by Vendor C DSS***
- 1668 • Functional profiles supported
- 1669 ○ HL7-I DssFP_CoreFunctionality
- 1670 • Semantic profiles supported
- 1671 ○ HL7-I DssSP_AllKmsSupport_CoreKmTraitReq
- 1672 ○ HL7-I DssSP_SomeKmsSupport_ContextSensitiveInfoRetrievalMediatorKm

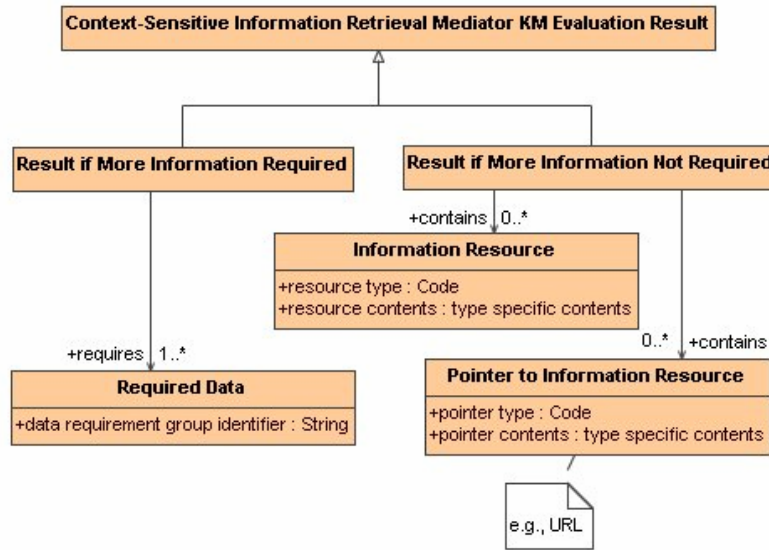
1673 **14.8.2 Sample Knowledge Modules Hosted by DSS C**

1674 14.8.2.1 Sample Context-Sensitive Information Retrieval Mediator Knowledge Module

- 1675 - KM identifying information:
- 1676 o Scoping entity identifier: Vend-C
- 1677 o KM identifier: context_sensitive_information_retrieval
- 1678 o Version: 1.00
- 1679 o Status: In Production
- 1680 - KM requirements fulfilled by KM:
- 1681 o HL7-I KmReq_CoreKmTraitReq
- 1682 o HL7-I KmReq_ContextSensitiveInfoRetrievalMediatorKm
- 1683 ▪ HL7-I KmReq_ContextSensitiveInfoRetrievalMediatorKm_EvalResultDef
- 1684 ▪ HL7-I KmReq_ContextSensitiveInfoRetrievalMediatorKm_DataReqSpecification
- 1685 - KM traits:
- 1686 o StewardOrganization → Vendor C
- 1687 o AuthorList → Kensaku Kawamoto, Ph.D.
- 1688 o CreationDate → 2006-06-22T19:59:00
- 1689 o LastReviewDate → 2006-06-22T19:59:00
- 1690 o VersionHistory → 2006-06-22T19:59:00 – initial creation by Kensaku Kawamoto, Ph.D.
- 1691 o KeywordListEnglishFreeText → “Infobutton manager”, “context-sensitive information retrieval manager”
- 1692 o KeywordListCodedValue → above concepts represented as coded values
- 1693 o Purpose → “The purpose of this knowledge module is to facilitate the retrieval of context-sensitive reference information at
- 1694 the point of care.”
- 1695 o Explanation → “This knowledge module utilizes patient data and user context data to deliver context-sensitive reference
- 1696 information.”

1697

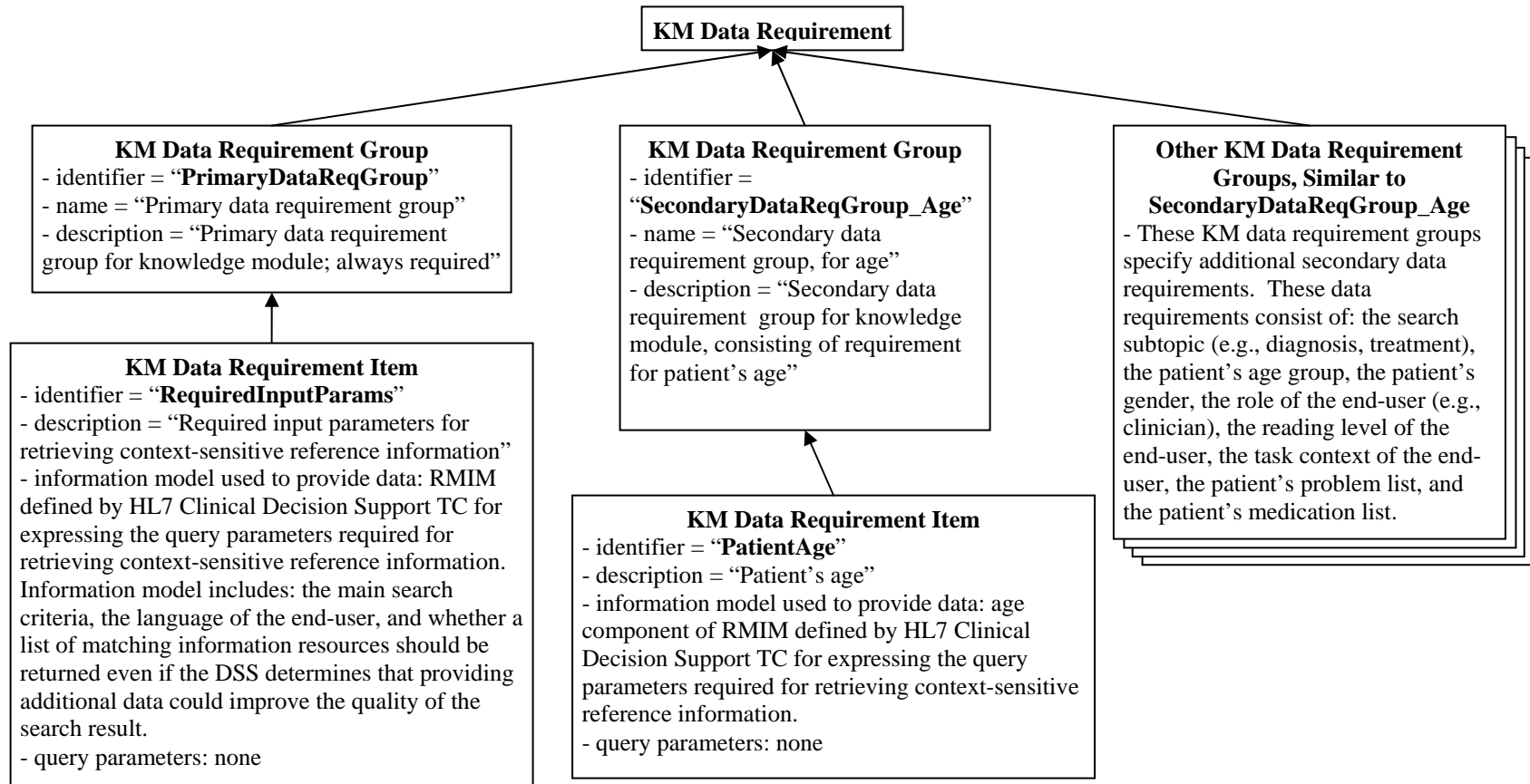
- KM evaluation result information model:



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- KM data requirements:



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- 1701 **14.9 Vendor D DSS (DSS D)**
- 1702 ***14.9.1 Profiles Supported by Vendor D DSS***
- 1703 • Functional profiles supported
- 1704 ○ HL7-I DssFP_CoreFunctionality
- 1705 • Semantic profiles supported
- 1706 ○ HL7-I DssSP_AllKmsSupport_CoreKmTraitReq
- 1707 ○ HL7-I DssSP_SomeKmsSupport_ContextSensitiveInfoProviderKm

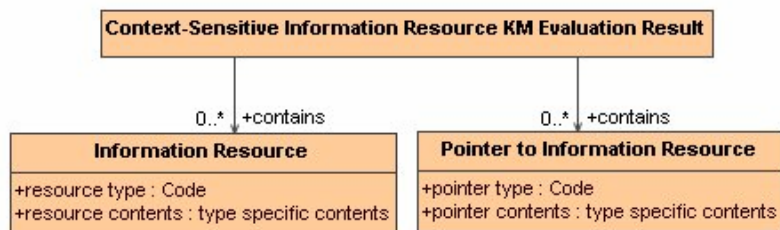
1708 **14.9.2 Sample Knowledge Modules Hosted by DSS D**

1709 14.9.2.1 Sample Context-Sensitive Information Provider Knowledge Module

- 1710 - KM identifying information:
 - 1711 ○ Scoping entity identifier: Vend-D
 - 1712 ○ KM identifier: context_sensitive_information_provider
 - 1713 ○ Version: 1.00
 - 1714 ○ Status: In Production
- 1715 - KM requirements fulfilled by KM:
 - 1716 ○ HL7-I KmReq_CoreKmTraitReq
 - 1717 ○ HL7-I KmReq_ContextSensitiveInfoProviderKm
 - 1718 ■ HL7-I KmReq_ContextSensitiveInfoProviderKm_EvalResultDef
 - 1719 ■ HL7-I KmReq_ContextSensitiveInfoProviderKm_DataReqSupersetSpecification
 - 1720 ■ HL7-I KmReq_ContextSensitiveInfoProviderKm_TraitDef
- 1721 - KM traits:
 - 1722 ○ StewardOrganization → Vendor D
 - 1723 ○ AuthorList → Kensaku Kawamoto, Ph.D.
 - 1724 ○ CreationDate → 2006-07-15T11:06:00
 - 1725 ○ LastReviewDate → 2006-07-15T11:06:00
 - 1726 ○ VersionHistory → 2006-07-15T11:06:00 – initial creation by Kensaku Kawamoto, Ph.D.
 - 1727 ○ KeywordListEnglishFreeText → “e-Resource”, “context-sensitive information resource”
 - 1728 ○ KeywordListCodedValue → above concepts represented as coded values
 - 1729 ○ Purpose → “The purpose of this knowledge module is to provide context-sensitive reference information at the point of
 - 1730 care.”
 - 1731 ○ Explanation → “This knowledge module utilizes patient data and user context data to deliver context-sensitive reference
 - 1732 information.”
 - 1733 ○ ContextSensitiveInfoProvider_AvailableContent → Specification of the information resources available through the KM.
 - 1734 Can specify, for example, that English-language resources meant for clinicians as well as patients are available regarding
 - 1735 common and rare genetic diseases.

1736

- KM evaluation result information model:



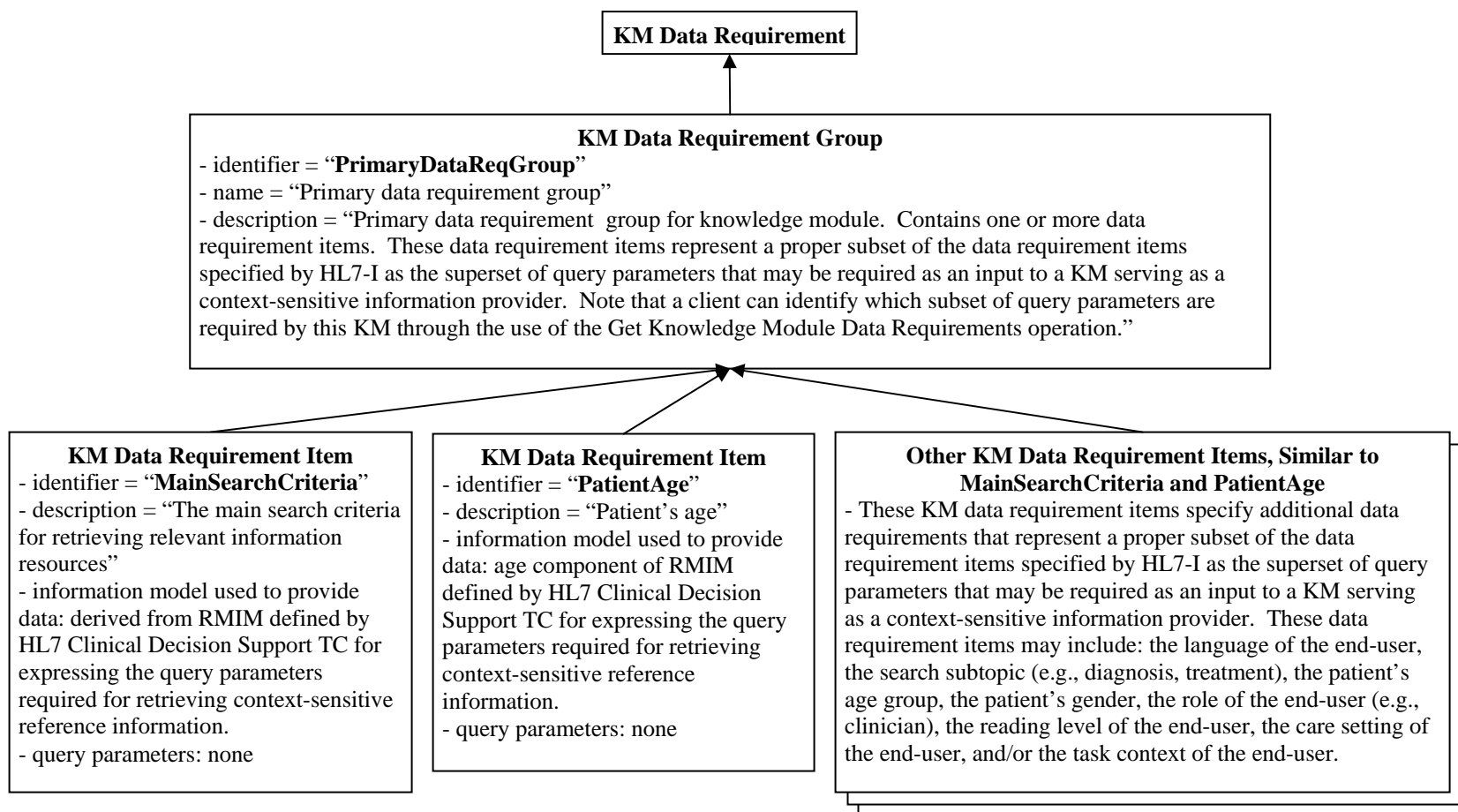
1737

1738

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- KM data requirements:



15 Appendix III: Reference Content for Business Scenarios (Non-Normative)

This section contains non-normative content referenced in the business scenarios.

Care Topic	Care Focus	Recommendation	Relevant Data	Guideline
Diabetes mellitus	Hemoglobin A1C test	Order hemoglobin A1C test (order)	<u>Last result</u> : 6.7 % on 2/15/05 (1 yr. 3 mo. ago)	Monitor q3months if last hemoglobin A1c \geq 7%, q6months otherwise (info)
Diabetes mellitus	LDL cholesterol test	Order LDL cholesterol test (order)	<u>Last result</u> : 120 mg/dL on 2/15/05 (1 yr. 3 mo. ago)	Monitor q12months (info)
Diabetes mellitus	Total cholesterol test	Order total cholesterol test (order)	<u>Last result</u> : 203 mg/dL on 2/15/05 (1 yr. 3 mo. ago)	Monitor q12months (info)
Diabetes mellitus	Retinal exam	Order retinal exam referral (order)	<u>Last done</u> : 4/3/04 (2 yr. 1 mo. ago)	Monitor q12months (info)
Diabetes mellitus	Pneumococcal vaccine	Order pneumococcal vaccination (order)	<u>Last done</u> : 1/28/94 (12 yr. 4 mo. ago)	Vaccinate if never vaccinated; if vaccinated 5+ years ago when patient was < 65 years old, revaccinate (info)
Preventive care	Colon cancer screening	Order colonoscopy (order)	<u>Last done</u> : none on record	Monitor q10 years via colonoscopy if \geq 50 years old (info)
Preventive care	Breast cancer screening	Order mammogram (order)	<u>Last done</u> : 2/26/04 (2 yr. 3 mo. ago)	Monitor q24months if \geq 40 years old (info)

Figure 5. Reference content for business scenario in Section 7.1.2.1. Screenshot from care recommendation section of Jane's patient summary screen.

```

1747 <?xml version="1.0" encoding="UTF-8"?>
1748 <careReminderSystemConfig>
1749   <gateKeeperKnowledgeModule scopingEntity="Vend-A" identifier="cdm_gatekeeper" version="1.00"/>
1750   <careTopic displayName="Diabetes mellitus">
1751     <careFocus displayName="Hemoglobin A1C test">
1752       <knowledgeModule scopingEntity="Vend-A" identifier="diabetes_need_for_hgba1c_test" version="1.00"/>
1753       <!-- The evaluation result of this KM contains a result code that defines the fundamental finding of the KM. The potential result codes that can
1754 be returned, and the meaning of these result codes, is described in a KM trait. For this KM, a result code of 001 signifies the patient does not have diabetes; a result code
1755 of 002 signifies the patient does have diabetes but is not due for a hemoglobin A1c test; and a result code of 003 signifies the patient does have diabetes and is due for a
1756 hemoglobin A1c test. -->
1757       <actionForResultCode code="001" displayCareRecommendation="No"/>
1758       <actionForResultCode code="002" displayCareRecommendation="No"/>
1759       <actionForResultCode code="003" displayCareRecommendation="Yes">
1760         <recommendationSection>
1761           <text>Order hemoglobin A1C test</text>
1762           <emphasis>Strong</emphasis>
1763           <includeOrderLinkIfOrderActsReturned>Yes</includeOrderLinkIfOrderActsReturned> <!-- Any orders that should be placed
1764 are returned as part of the evaluation result as HL7 v3 Acts in the order mood. These orders can be placed from the care recommendation summary by clicking on the
1765 "order" link.-->
1766         </recommendationSection>
1767         <relevantDataSection>
1768           <relevantDataItemToDisplay>last_result</relevantDataItemToDisplay> <!-- The evaluation result of this KM contains name-
1769 value pairs of result parameters. The configuration parameter "last_result" specifies that the "last_done_date_time", "time_since_last_done", "last_done_value", and
1770 "last_done_value_unit" should be used to generate an entry in the relevant data section in the format illustrated in the screenshot provided earlier. -->
1771         </relevantDataSection>
1772         <guidelineSection>
1773           <guidelineSummaryTextToUse>km_short_guideline_explanation</guidelineSummaryTextToUse> <!-- Indicates that the
1774 short (<= 100 characters) English explanation of the underlying clinical guideline provided as a KM trait should be used. This text could be replaced in the configuration
1775 file, e.g., if the system needs to be deployed in a country with a language other than English. -->
1776           <guidelineDetailedTextToUse>km_long_guideline_explanation</guidelineDetailedTextToUse> <!-- Indicates that the long
1777 English explanation of the underlying clinical guideline provided as a KM trait should be used to populate the detailed explanation of the clinical guideline that is provided
1778 when the "info" link is clicked from the care recommendation summary. This text also could be replaced in the configuration file, e.g., if the system needs to be deployed
1779 in a country with a language other than English.-->
1780         </guidelineSection>
1781       </actionForResultCode>
1782     </careFocus>
1783     <!-- Multiple other careFocus definitions would be specified here (e.g., for the evaluation of whether a patient with diabetes is due for a pneumococcal
1784 vaccination) -->
1785   </careTopic>
1786   <!-- Multiple other careTopic definitions would be specified here (e.g., for preventive care or for congestive heart failure management) -->
1787 </careReminderSystemConfig>

```

1788 **Figure 6.** Reference content for business scenario in Section 7.1.2.1. XML configuration file illustrating how evaluation results returned by a DSS can
1789 be used to meet a context-specific CDS need.

16 Appendix IV: HL7 EHR Functional Model Traceability

1791

1792

1793 *This section lists the EHR Functions that are related to this service.*

1794 *Note that in general there will not be a direct correspondence between EHR Functions and HSSP Services, since Services are specified from*
1795 *a different system viewpoint. The mapping provided here enables the HSSP Services to be understood in the context of the **EHR-S***
1796 ***Functional Model DSTU**.*

1797

1798 This SFM does not specify EHR functions related to a DSS at a granular level. However, it is noted that a DSS could be used to support
1799 many of the Clinical Decision Support functions specified in Section C.2 of the EHR functional model as specified in the July 2004 DSTU
1800 ballot package.