



1 March 15, 2010

2

3 The Honorable Kathleen Sebelius
4 Secretary of Health and Human Services
5 U.S. Department of Health and Human Services
6 200 Independence Avenue, SW
7 Washington, DC 20201

8

9 Charlene Frizzera
10 Acting Administrator
11 Centers for Medicare and Medicaid Services
12 7500 Security Boulevard
13 Baltimore, MD 21244

14

15 Dear Secretary Sebelius and Administrator Frizzera:

16

17 On behalf of the Board of Directors and members of the Healthcare Information and
18 Management Systems Society (HIMSS), we are pleased to submit written comments on
19 the Department of Health and Human Services (HHS) Notice of Proposed Rule Making
20 (NPRM), entitled, *Medicare and Medicaid Programs; Electronic Health Record*
21 *Incentive Program [CMS – 0033—P; RIN 0938 – AP78]* that was posted in the Federal
22 Register on January 13, 2010.

23

24 HIMSS is the healthcare industry's membership organization exclusively focused on
25 providing leadership for the optimal use of healthcare information technology and
26 management systems for the betterment of healthcare. HIMSS represents more than
27 27,000 individuals, 400 corporate members, more than 50 non-profit organizations, and
28 46 chapters nationwide. HIMSS seeks to shape healthcare public policy and industry
29 practices through its educational, professional development, and advocacy initiatives
30 designed to promote information and management systems' contribution to quality
31 patient care.

32

33 As in past responses to HHS, HIMSS has leveraged the subject matter expertise of our
34 members to ensure that our response reflects the broadest level of industry experience.
35 For the response on the guidance document, HIMSS developed a cross-organization work
36 group that represents the expertise of our overall membership. In addition, HIMSS
37 sought input on the response from our steering committee structure, including the
38 following areas of expertise: Ambulatory Information Systems; Enterprise Information
39 Systems; Financial Information Systems; Healthcare Information Exchange;
40 Management Engineering and Process Improvement; Nursing Informatics; Physician
41 Community; Patient Safety & Quality Outcomes; Personal Health Records; Privacy and
42 Security; and Public Policy. We also sought the expertise of our Chapter Advocates
43 Roundtable and Legislative & Regulatory Review Task Force to ensure the HIMSS
44 response would reflect the diversity of our membership. In addition, we have also

45 leveraged the subject matter expertise of our colleagues at the Electronic Health Record
46 Association and the Joint Public Health Informatics Task Force, on issues related to EHR
47 software development and public and population health requirements, respectively.
48

49 HIMSS appreciates the Department’s interest in seeking public comment on this issue,
50 and offers the following observations that were approved by our Board of Directors.
51 Most importantly, we thank the Department and CMS for undertaking this landmark
52 regulation.
53

54 **Overview and Summary of Recommendations**

55 HIMSS recommends modifications to the NPRM that accomplish the following themes:
56 (Corresponding line numbers in parentheses)

- 57 1. **Incentive Program Eligibility and CCN:** Corrects the unintended impact of using
58 CMS Certification Numbers (CCN) to identify hospitals for incentive payments.
59 (lines 142-164)
- 60 2. **Incentive Program Eligibility and POS:** Clarifies the definition of hospital-based
61 professionals (HBPs) to reflect Congressional intent to consider the EHR the provider
62 is using as well as Place of Service (POS) settings, reducing substantially the number
63 of professionals who are excluded from incentives as HBPs. (lines 166-216)
- 64 3. **Criteria for Meaningful Use:** Provides an alternate approach to the current “All or
65 Nothing” approach to Meaningful Use by streamlining criteria recognizing the
66 impact on workflow; placing an emphasis on more realistic percentages for metrics;
67 eliminating some metrics; and allowing some objectives and measures to be deferred
68 to Stage 2. (lines 220-743)
- 69 4. **Clinical Quality Measures for Meaningful Use:** Significantly reduce the number of
70 Clinical Quality Measures ensuring that measures can be health IT-enabled as part of
71 the care process. (lines 745-855)
- 72 5. **Health Information Exchange (HIE):** Supports the government’s intent to
73 accelerate the use of HIE as capabilities increase after Stage 1, and also suggests that
74 the government place more emphasis on standards-based HIEs in the meaningful use
75 requirements. (lines 857-860)
- 76 6. **Privacy and Security:** Supports adherence to existing privacy and security law and
77 regulation without creating duplicate regulatory requirements. (lines 702-743)
- 78 7. **Certification Criteria:** Supports the ability of non-certified technology to be
79 employed to support certified EHR technology to help providers achieve meaningful
80 use, so long as the provider also uses certified EHR technology as defined in the ONC
81 Interim Final Rule on *Standards, Implementation Specifications, and Certification*
82 *Criteria for Meaningful Use* (lines 1046-1071).
- 83 8. **Health IT Implementation Timelines:** Recognizes the impending strain on the
84 healthcare community from the potential “Perfect Storm” of health IT project
85 timelines required for Meaningful Use and the associated Standards and Certification
86 Criteria, along with the conversion to ICD-10 and ASC X12 5010 standard.
87

88 HIMSS members strongly support moving forward on the development of a system of
89 interoperable healthcare IT, including the Nationwide Health Information Network,

90 which includes the maximum participation by all clinician categories and healthcare
91 delivery settings. A critical first step is ensuring that eligible providers can achieve
92 adoption and meaningful use of qualified, certified, EHR technology. Clearly, the goal of
93 such adoption and use increases access, quality, and efficiency. Thus, while the
94 Medicaid and Medicare incentive programs should emphasize improvement in these
95 areas as an end result, we should also be mindful that adoption of the right technologies
96 must precede its meaningful use.

97
98 Ultimately, these incentive programs should be expanded to try to include as many
99 practicing clinicians and other health care providers, whether they practice in rural,
100 underserved, or metropolitan areas, as possible to move them as soon as possible to a
101 carefully planned program of ongoing improvement in quality of care supported through
102 the use of health IT. The greatest improvement in quality of care overall for all patients
103 can only occur if as many providers as possible can participate.

104
105 HIMSS recognizes that the definitions for eligible professionals and hospitals were
106 dictated in ARRA, and that the Department and CMS are working under clearly defined
107 legislative guidance. We anticipate working with other healthcare IT stakeholder groups
108 and Congress to engage additional eligible professional categories over the course of the
109 timeline for the *Medicare and Medicaid Programs; Electronic Health Record Incentive*
110 *Programs* on such action items as:

- 111 • Expanding the definition of “meaningful user” to encompass support of all
112 healthcare professionals in an integrated healthcare community.
- 113 • Expanding the care delivery setting to encompass more parts of the continuum of
114 care, including long-term, community-based, home care, and public health-based
115 settings, whereby data and information necessary for managing these populations
116 is shared.
- 117 • Collecting standardized clinical performance measures as a byproduct of care
118 delivery and clinician documentation that support workflow and improve care
119 delivery by incorporating existing National Voluntary Consensus Standards for
120 Nursing-Sensitive Care.
- 121 • Enhancing programs and funding availability for patient education offerings
122 and the advancement of personal health records and how to leverage
123 patients’ personal health information to improve clinical outcomes.

124
125 It is essential that the Department and CMS reconsider the proposal and comments in the
126 context of the stated congressional goal of providing incentives for adoption of
127 interoperable EHRs that actually increase adoption. The incentive structure that was put
128 in place, including the actual dollar levels, did not anticipate the level of detail for
129 meaningful use and associated compliance costs and compliance-related uncertainties
130 that have emerged over the past several months.

131 We suggest the Department and CMS fine-tune the approach to meaningful use to assure
132 that it will actually incentivize the greatest number of providers to adopt and use
133 interoperable comprehensive EHRs, recognizing that different users will attach different

134 priorities to specific areas of EHR functionality. As we have seen with recent innovative
135 technologies, users will find "meaningful use" in various ways that enable the most
136 productive use in their local environment beyond the very specific expected value of any
137 given component or application

138 Given this last point, we ask the Department and CMS to shift the balance from highly
139 detailed meaningful use criteria/measures and very aggressive timelines to a smaller
140 number of required criteria/measures with lower thresholds for achievement.

141 Our specific recommendations are outlined below.

142 **CMS Certification Numbers:**

143 HIMSS and our members have interpreted congressional intent in the American
144 Recovery and Reinvestment Act of 2009 as being clear that the eligible hospital incentive
145 program was intended to be available at the individual facility level. Using congressional
146 intent as the baseline, HIMSS has a concern about the practical application of the use of
147 the CCN to identify hospitals for the Medicare EHR Incentive Program.

148
149 HIMSS has been made aware that the use of the CCN may have a limiting effect on
150 eligible hospitals and hospital systems' ability to receive the incentive payments intended
151 by Congress. The specific concern involves multi-facility organizations and whether or
152 not multiple eligible hospitals bill under one CCN. Each facility requires resources for
153 workflow redesign, change management activities, process improvement, training,
154 software, hardware, etc.

155
156 As written, the NPRM would only pay once per CCN, regardless of number of hospitals
157 within a system. An informal polling of hospital systems determined that 50% utilize one
158 CCN for the system, while the other 50% applied for and utilize one CCN per facility.
159 Therefore, the CCN may unintentionally keep eligible hospitals from receiving the full
160 level of incentive payment, running counter to clear congressional intent.

161
162 HIMSS suggests two complementary solutions may include basing incentive payments
163 on distinct physical locations, perhaps limited by a distance criteria, or using a
164 combination of CCN and the facility address to make the determination.

165
166 **Hospital-based Eligible Professionals**

167 As we stated in the general comments, HIMSS supports the prospect of maximizing the
168 number of providers who utilize health IT to improve access to quality and cost effective
169 care. The Medicare and Medicaid EHR Incentive Programs are intended to incentivize
170 behavior among eligible professionals. HIMSS is concerned the current language of the
171 proposed rule departs from the statutory language that the provider must meet all criteria
172 (both site of service and use of hospital facilities and equipment, including qualified EHR
173 of the hospital) in order to be deemed a hospital-based provider.

174

175 (ii) *HOSPITALBASED ELIGIBLE PROFESSIONAL.*—For purposes of clause (i),
176 the term ‘hospital based eligible professional’ means, with respect to covered
177 professional services furnished by an eligible professional during the EHR
178 reporting period for a payment year, an eligible professional, such as a
179 pathologist, anesthesiologist, or emergency physician, who furnishes substantially
180 all of such services in a hospital setting (whether inpatient or outpatient) and
181 through the use of the facilities and equipment, including qualified electronic
182 health records, of the hospital. The determination of whether an eligible
183 professional is a hospital based eligible professional shall be made on the basis of
184 the site of service (as defined by the Secretary) and without regard to any
185 employment or billing arrangement between the eligible professional and any
186 other provider.
187

188 The proposed rule will have a limiting effect on the ability of otherwise eligible
189 professionals working in an outpatient clinic setting of a hospital or Integrated Delivery
190 System (IDS) to maximize involvement in the EHR Incentive Payment Programs. For
191 example, each hospital ambulatory clinic implementing an EHR requires resources for
192 workflow redesign, change management activities, process improvement training,
193 software, hardware, etc., which are separate from activities engaged in the hospital
194 setting.
195

196 The Department and CMS may have inadvertently narrowed the scope of the legislation
197 by focusing solely on specific Place of Service (POS) codes to define hospital-based
198 professionals.
199

200 According to CMS’s own calculations, a full one-third of otherwise eligible professionals
201 will be deemed ineligible under the current definition of hospital-based professionals.
202

203 We propose the Department and CMS adopt a narrower definition of hospital-based
204 eligible professional, consistent with the ARRA statutory language and Congressional
205 intent. In particular, we urge that, as this category of provider was defined in ARRA, the
206 Department and CMS consider the certified EHR the EP (eligible provider) is using in
207 addition to place of service code.
208

209 Specifically, we propose that a hospital-based EP would be defined as one who provides
210 90% of his/her services, defined as encounters and not as charges (to align best with time
211 spent), in a hospital setting as proposed by the Department and CMS, and that the EP also
212 use the hospital inpatient-certified EHR to support the care s/he provides in this setting.
213 This approach would mean that if the professional is using an ambulatory-certified EHR
214 technology, s/he would not be considered a hospital-based EP. Eligible professionals, as
215 part of their attestation process, should attest that they are not hospital-based eligible
216 professionals as per the proposed new definition above.
217
218
219

220 **Criteria for Meaningful Use**

221 HIMSS applauds the use of criteria to help eligible professionals and hospitals determine
222 their capabilities for achieving meaningful use of certified EHR products. However, we
223 have some concerns as well.

224

225 The NPRM currently requires:

- 226 • EPs and hospitals to report on more than 20 functional measures addressing use of
227 specific health IT capabilities, such as recording vital signs, problem lists and
228 demographics, and using CPOE (computerized provider order entry) and reminders.
- 229 • A large percentage of measures require reporting a number and denominator, with
230 several denominators requiring data that is not captured by the EHR.
- 231 • Generally very high thresholds must be demonstrated and met.
- 232 • EPs are required to submit reports of clinical outcomes based on a set of core
233 measures plus a subset of measures most appropriate to the EP’s specialty.
- 234 • Eligible hospitals are required to report up to 43 summary quality measures for
235 applicable cases (35 for Medicare plus eight optional measures for Medicaid).

236

237 All objectives and thresholds must be met to achieve the incentive.

238

239 Our members have expressed considerable concern about the large number of measures
240 with very high thresholds and the “all or nothing” approach to compliance. We believe
241 that the measures associated with the criteria are too stringent for Stage I. In most cases,
242 80% compliance is a difficult level to achieve when eligible providers are relearning
243 workflow and the other challenges associated with implementing certified EHR
244 technology. In addition, there are substantial measurement challenges for many of these
245 measures, especially those that require denominators to be calculated with non-EHR data
246 (i.e. managing patient interactions).

247

248 Stage I should focus on having eligible providers begin to use the EHR and reporting on
249 baseline quality measures, with much less focus on specific percentages. Even if a
250 provider strives for meaningful use and is aggressive about achieving every objective,
251 measure, and clinical quality measures, a small oversight or element beyond their control
252 could cause them to not qualify for the incentives (e.g., an EP might meet every objective
253 and measure but come in at 79% for the problem list).

254

255 Even if each objective and measure makes sense on its own--and we do have concerns
256 with some specific objectives and measures--the combination of all of the requirements
257 creates implementation challenges, with too much complexity to be managed in such
258 short timeframes.

259

260 HIMSS encourages the Department and CMS to allow some flexibility in meeting
261 meaningful use criteria. The “all or nothing” approach as currently written will be very
262 difficult for most providers to reach as they seek to address the extensive array of
263 objectives and measures. Allowing providers access to more realistic success thresholds,
264 along with some flexibility in which objectives to focus on, will have a positive impact

HIMSS Comments on Medicare and Medicaid Programs; Electronic Health Record Incentive Program [CMS – 0033—P; RIN 0938 – AP78]

265 on participation in the Incentives program. We support the general concept that was
266 outlined by the HIT Policy Committee recommendation #12 of its letter to the Office of
267 the National Coordinator on February 17, 2010 and allowing providers to select some
268 mandatory and allowing them to defer a small number of other measures from most
269 measure sections is the correct approach for Stage I.

270
271 We provide specific recommendations by objective and measure below.

272
273 Computerized Provider Order Entry (CPOE)

274 Department and CMS Requirement as identified in the NPRM

275 Objective: EPs use CPOE; Eligible hospitals CPOE for orders (any type)
276 directly entered by authorized provider (for example MD, DO, RN,
277 PA, NP)

278 Measure: For EPs: CPOE is used for at least 80% of all orders
279 For eligible hospitals: CPOE is used for 10% of all orders

280
281 HIMSS Observations on Computerized Provider Order Entry Criteria:

282
283 EPs and CPOE:
284 80% CPOE requirements for EPs is too high, especially given the challenge of
285 collecting denominator information on all orders from outside the EHR and the
286 focus on use by the authorizing provider. HIMSS recommends setting the
287 requirement at 50%.

288
289 Eligible Hospitals and CPOE:
290 HIMSS cautions the Department and CMS that 10% may be difficult for hospitals
291 that have not begun implementing and are implementing on a department-by-
292 department basis.

293
294 Implement Drug-Drug, Drug-Allergy, Drug-Formulary Checks

295 Department and CMS Requirement as identified in the NPRM

296 Objective: Implement Drug-Drug, Drug-Allergy, Drug-Formulary Checks
297 Measure: The EPs/Eligible hospitals have enabled this functionality

298 HIMSS Observations on Drug-Drug, Drug-Allergy, and Drug-Formulary Checks:
299 HIMSS supports the measures, with the request that the Department and CMS
300 clarify the references to Medicare Part D, as that program would not be relevant
301 to eligible hospitals.

302 Problem Lists

303 Department and CMS Requirement as identified in the NPRM

304 Objective: Maintain an up-to-date problem list of current and active diagnoses
305 based on ICD-9-CM or SNOMED CT

306 Measure: At least 80% of all unique patients seen by the EP or admitted to
307 the eligible hospital have at least one entry or an indication of none
308 recorded as structured data

309 HIMSS Observations on Problem Lists:
310 We ask the Department and CMS to clarify that, per the approach taken by the
311 HIT Standards Committee; the specified vocabulary should be for interoperability
312 between entities and not within an entity. Content should be able to be represented
313 in the specified vocabularies and exchanged in the specified standards at the
314 boundary between entities, regardless of how it is managed internally. Many
315 methods may potentially be used to meet interoperability standards (e.g.,
316 mapping, external services, or native data capture). We also ask the Department
317 and CMS to clarify that the problem list can be based on problems at discharge.

318
319 For Eligible Hospitals, HIMSS recommends the Department and CMS review the
320 requirement for coded vs. uncoded data in Stage I, and given the complexity of
321 implementing problem list changes to workflow requirements, that perhaps a 10%
322 threshold should be required, which would be consistent with the requirement for
323 CPOE. HIMSS reminds the Department and CMS that a 10% threshold may be
324 difficult for hospitals have not begun implementing and are implementing on a
325 department-by-department basis.

326
327 Electronic Prescribing

328 Department and CMS Requirement as identified in the NPRM

329 Objective: Generate and transmit permissible prescriptions electronically

330 Measure: At least 75% of all permissible prescriptions written by the EP are
331 transmitted electronically using certified EHR technology

332
333 HIMSS Observations on Electronic Prescribing:
334 It may be difficult to get to 75% with the exclusion of scheduled drugs and
335 pharmacies that don't use e-Prescribing. EPs today also still have significant
336 issues ensuring that participating pharmacies can successfully receive the
337 transmissions as submitted by the provider. Often the physician transmits the
338 prescription and it is not received by a pharmacy.

339
340 In addition, systems will need to be able to track percentages of eligible
341 prescriptions written that are transmitted electronically; most (if not all) do not
342 now. The measurement should also address receipt of the prescription as verified
343 by the pharmacy, hence including the pharmacy and technology partners into the
344 process.

345
346 The percentage should be no higher than 50%, which is what CMS had used in its
347 E-Prescribing incentive program.

348
349 As HIMSS has indicated in the past, the adoption and utilization of electronic
350 prescribing tools will be limited until the federal government allows electronic
351 prescribing of controlled substances. HIMSS members continue to remind
352 readers that the current Drug Enforcement Agency (DEA) requirement for
353 providers to use paper prescriptions for Class II Controlled Substances is
354 hampering adoption of health IT solutions. Workflow, particularly in the
355 ambulatory and outpatient settings, is severely hampered by the dual tracked
356 prescription system. We strongly encourage the Department and CMS to
357 continue working with the Obama Administration and the DEA to finalize the
358 DEA rule, so this obstacle to adoption of EHRs and associated E-Prescribing
359 capabilities can be mitigated.

360

361 Maintain Active Medication List

362 Department and CMS Requirement as identified in the NPRM

363 Objective: Maintain active medication lists
364 Measure: At least 80% of all unique patients seen by the EP or admitted to
365 the eligible hospital have at least one entry (or an indication of
366 “none” if the patient is not currently prescribed any medication)
367 recorded as structured data

368

369 HIMSS Observations on Maintaining Active Medication List:
370 The measure is going to be difficult for many EPs and eligible hospitals to meet.
371 The challenge will be determining the correct numerator number. HIMSS
372 suggests clarifying the process for identifying the patients seen during the
373 reporting period.

374

375 Record Demographics

376 Department and CMS Requirement as identified in the NPRM

377 Objective: Record demographics, preferred language, insurance type, gender,
378 race, ethnicity, and date of birth
379 Measure: At least 80% of all unique patients seen by the EP or admitted to
380 the eligible hospital have demographics recorded as structured data

381

382 HIMSS Observations on Recording Demographics:
383 Generally speaking, these measures are collected in the Practice Management
384 System (PM) or Admission Discharge Transfer System (ADT), not the EHR,
385 although we recognize that many EPs and hospitals do have integrated
386 clinical/financial systems. We ask that the Department and CMS reduce the
387 threshold percentages to reflect the complicating fact that in many cases these
388 data are not collected using the EHR.

389

390

391 Clinical Labs Data Collection

392 Department and CMS Requirement as identified in the NPRM

- 393 Objective: Incorporate clinical lab-test results into EHR as structured data
394 Measure: At least 50% of all clinical lab tests ordered whose results are in a
395 positive/negative or numerical format are incorporated in certified
396 EHR technology as structured data

397

398 HIMSS Observation on Clinical Labs Data Collection:

399 Currently, many labs do not today and will not create interfaces to/from smaller
400 provider offices. It is not clear how this will be accomplished since there is no
401 incentive for labs to cooperate and so the cost will need to be borne by the
402 practices. This requirement should only apply to data received using the
403 standards and format specified in the ONC Interim Final Rule. Finally, the update
404 requires a "user intervention;" it should be able to update automatically.

405

406 Vital Signs

- 407 Objective: Record and chart changes in vital signs, height, weight, blood
408 pressure. Calculate and display BMI, plot and display growth
409 charts for children 2-20 years, including BMI.

- 410 Measure: For at least 80% of all unique patients age 2 and over seen by the
411 EP or admitted to eligible hospital, record blood pressure and BMI;
412 additionally plot growth chart for children age 2-20.

413 HIMSS Observations on Vital Signs:

414 While there is value in measuring height and weight to determine a child's health
415 comparable to accepted age-level guidelines, requiring growth charts including
416 the identified measures has limited application in the hospital context unless the
417 patient is seen at a children's hospital. This measure sets a very high bar for a
418 function that would be used infrequently in the hospital setting. The Department
419 and CMS should consider requiring hospitals to capture the data points for height
420 and weight, while attesting that the function for calculation is enabled without
421 requiring a percentage to be reported.

422

423 Smoking Cessation Tracking

424 Department and CMS Requirement as identified in the NPRM

- 425 Objective: Record smoking status for patients 13 years old or older.
426 Measure: At least 80% of all unique patients 13 years old or older seen by
427 the EP or admitted to the eligible hospital have "smoking status"
428 recorded

429

430 HIMSS Observation on Smoking Cessation Tracking:

431 HIMSS is concerned that the measure will be too challenging in Stage I,
432 particularly for practices that are just beginning the implementation process. In
433 some instances, HIMSS has heard that hospitals are recording this information for
434 all patients. Others point to the issues that have emerged about data validity
435 based on the experience of tracking. Additionally, capturing and reporting this
436 information could have financial implications for insured individuals, which will
437 create a disincentive to report accurately.

438

439 Generate Type, Conditions, Quality Measure Reports

440 Department and CMS Requirement as identified in the NPRM

441 Objective: Generate lists of patients by specific conditions to use for quality
442 improvement, reduction of disparities, and outreach

443 Measure: Generate at least one report listing patients of the EP or eligible
444 hospital with a specific condition

445

446 HIMSS Observations on Quality Measure Reports:

447 In general, HIMSS concurs with this measure, and requests the government clarify
448 what is meant by a "condition" and consider defining it as an item from the problem
449 list.

450

451 Reporting Ambulatory and Hospital Quality Measures to CMS and States

452 Department and CMS Requirement as identified in the NPRM

453 Objective: EPs Report Ambulatory quality measures to CMS or the states;
454 Eligible Hospitals report hospital quality measures to CMS or the
455 states

456 Measure: For 2011, provide aggregate numerator and denominator through
457 attestation as discussed in section II (A)(3) of the proposed rule.
458 For 2012, electronically submit the measure as discussed in section
459 II (A)(3).

460

461 HIMSS Observation on Ambulatory and Hospital Quality Measures to CMS/States:
462 HIMSS recommends the Department and CMS review the detailed quality
463 recommendations below.

464

465 HIMSS has conducted a considerable amount of written and verbal dialogue among
466 our members regarding the Quality Metrics, which has resulted in a series of
467 recommendations. These recommendations are discussed at length later on pages
468 18-20 (lines 744-854) in our response.

469

470 Reminders and Prevention Messages to Patients

471 Department and CMS Requirement as identified in the NPRM

472 Objective: Send reminders to patients per patient preferences for preventive
473 follow up care

474 Measure: [For EPs] Reminder sent to at least 50% of all unique patients seen
475 by the EP that are age 50 or over

476

477 HIMSS Observation on Reminders and Prevention Messages to Patients:
478 HIMSS suggests that rather than demonstrating the capability, that EPs attest to
479 having the system in place to be able to deliver the reminders as needed.

480

481 Clinical Decision Support

482 Department and CMS Requirement as identified in the NPRM

483 Objective: Implement 5 clinical decision support rules relevant to specialty or
484 high clinical priority, including diagnostic test ordering, along with
485 the ability to track compliance with those rules

486 Measure: Implement 5 clinical decision support rules relevant to the clinical
487 quality metrics the EP/Eligible hospital is responsible for as
488 described further in section II (A)(3).

489

490 HIMSS Observation on Clinical Decision Support:
491 HIMSS notes that the required five clinical decision support rules have the potential
492 to improve care processes and outcomes, but also cautions strongly that they can
493 cause major problems in clinical workflow and care safety if not implemented with
494 great care. This risk is especially great given the tremendous time pressure on
495 providers to implement these rules, relative lack of widespread successful experience
496 with such rules, and the substantial complexity involved in successfully deploying
497 them.

498

499 Similar considerations apply to drug-drug interaction (DDI) alerting. Though
500 provider experience with this type of alerting is more widespread than alerting
501 focused on priority conditions, it is equally problematic. HIMSS recognizes that
502 ONC has released request for task order proposals to address these challenges.
503 HIMSS notes that it has led broad collaborations of individuals and organizations in
504 synthesizing best practices for successfully applying CDS (including condition-based
505 alerts and DDI notifications) to improve care processes and outcomes (see
506 www.himss.org/cdsguide). HIMSS is hopeful that such implementation guidance
507 from this organization and others are fully utilized within new ONC processes to
508 ensure that these CDS-related meaningful use requirements do more good than harm.

509

510 In addition, HIMSS suggests that no more than two of the 5 CDS rules should be
511 required to be linked to the utilized quality measures to allow for EP and hospitals to
512 focus on other applicable high priority clinical areas specific to their settings.

513

514 Finally, HIMSS suggests further clarification regarding the requirement to ‘track
515 compliance with those [5 CDS] rules.’ If the intention is that the 5 rules must be
516 workflow-interrupting alerts (which HIMSS would recommend against), then this
517 requirement might be taken to mean that the tracking refers to how the recipient

518 addresses the interruption (e.g. accepting the recommendation or overriding it). This
519 further suggests requirements for user interaction with the interruption, which raises
520 additional implementation complexities and risks of harm (e.g. related to alert
521 fatigue). Key measures of interest include whether the recommendation was
522 ultimately followed, not just how an interruption or other mechanism through which
523 the CDS intervention was delivered was handled. HIMSS believes this type of
524 measurement is beyond the scope of what can be accomplished in Stage 1, and
525 recommends deferring this assessment to Stage 2.

526

527 Insurance Eligibility

528 Department and CMS Requirement as identified in the NPRM

529 Objective: Check insurance eligibility electronically from public and private
530 payors

531 Submit claims electronically to public and private payors

532 Measure: Insurance eligibility checked electronically for at least 80% of all
533 unique patients seen by the EP or admitted to the eligible hospital

534 At least 80% of all claims filed electronically by the eligible
535 professional or eligible hospital.

536

537 HIMSS Observations on Insurance Reform:

538 HIMSS suggests that this requirement be clarified so that accomplishment of this
539 functionality can be achieved through a provider's practice management system, not
540 by directly accessing an insurer's eligibility system and/or the EHR system. We also
541 suggest that the 80% levels be reduced to 50%, which is more in line with current
542 industry practice.

543

544 HIMSS supports a push towards administrative simplification industry wide using the
545 Council on Operating Rules for Eligibility (CORE) process. HIMSS notes that
546 effective administrative simplification results can be realized when all stakeholders
547 support the CORE rules, which includes payers and payors clearing houses, as well as
548 the , software system vendors as well as providers. CORE rules are currently able to
549 support and facilitate administrative simplification as outlined in the MU
550 requirements. CORE Phase II is currently being implemented in the industry and we
551 look forward to maturation of eligibility verification based on CORE Phase II by
552 2014.

553 Engaging Patients and Families

554 Department and CMS Requirement as identified in the NPRM

555 Objective: Provide patients with an electronic copy of their health information
556 (including diagnostic test results, problem list, medication lists,
557 allergies), upon request

558 Measure: At least 80% of all patients who request an electronic copy of their
559 health information are provided it within 48 hours

560

561 HIMSS Observation on Engaging Patients and Families:

562 Eligible Professionals:

563 HIMSS has several concerns regarding these requirements. This criterion has been
564 criticized for requiring too short of a time frame, given that the applicable ARRA
565 privacy provision does not impose such a timeframe, does not allow enough time for
566 an eligible professional to review lab and radiology results and counsel the patient,
567 and is unduly burdensome in requiring a specific number of hours to be counted.
568

569 The Meaningful Use NPRM proposes that 80% of all patients receiving an electronic
570 copy of their “health information” receive it within 48 hours, that at least 10% of all
571 unique patients seen by an EP are provided timely electronic access to their health
572 information, and that at least 80% of all patients discharged from a hospital
573 requesting an electronic copy of their discharge instructions and procedures receive it
574 (“at the time of discharge”). These are very confusing standards in terms of scope
575 and duration and need to be harmonized with HIPAA and HITECH so that patients
576 can understand what their federal rights are and what the expectations are for
577 providers receiving Medicare and Medicaid stimulus payments.
578

579 Patients have a right under HIPAA §164.524 to request and receive their health
580 information, but that right is limited in certain ways. The scope of the disclosure is
581 limited to a designated record set, a defined term that includes medical records or
582 health information used to make decisions about the patient. Most covered entities do
583 not include in the definition of the legal health record working notes used by
584 providers in completing final reports or other official business records (other than
585 billing information) unless the information is used to make decisions about the
586 individuals. HIPAA permits covered entities to further limit disclosures of
587 psychotherapy notes and information compiled in anticipation of litigation or other
588 proceedings and to discuss the scope and format and other aspects of the information
589 disclosed as necessary and agree upon the format with the individual. 45 CFR
590 164.524 (c)(2)(i). Covered entities must act on a patient request for medical records
591 within 30 days, but may extend that period if records are offsite and an additional 30
592 days by providing written notice to the patient outlining the reasons for a delay and
593 the expected completion date. HITECH expands this federal right for all patients to
594 allow individuals the right to request PHI in an electronic format and to direct its
595 transmission to a designee by making a clear, conspicuous and specific choice. The
596 industry is awaiting rules from OCR on how it will implement this new HITECH
597 right.
598

599 The same limitations on the scope of the information provided under HIPAA should
600 be respected under the Meaningful Use rule (final information, relied on for
601 decisions about the individual, with exceptions for psychotherapy notes and attorney-
602 client privileged information).
603

604 In addition, the mechanics and security requirements of providing electronic copies
605 to patients also need to be addressed due to the need to encrypt or otherwise secure

606 e-mail and other technologies, which are some of the methods that could be used to
607 provide an electronic copy at an office visit. For example, the risk posed to an EP’s
608 IT system of interfacing with a patient’s thumb drive also needs to be taken into
609 account.

610
611 The requirement that 10% of patients receive “timely electronic access” to their
612 health information” within 96 hours after it is available to the EP may present even
613 more difficulty because it is not limited to patients who request such access. As
614 discussed in the preamble, the numerator for this measure will be the number of
615 unique patients seen during the EHR reporting period who have electronic access to
616 their health information (for example, have established a user account and password
617 on a patient portal). The denominator for this objective will be the number of unique
618 patients seen during the reporting period. HIMSS recognizes that many patients may
619 not have Internet access, or may not have the capability or interest to utilize patient
620 portals. Health systems that have actively promoted such technologies have been
621 able to achieve active use by over 30 percent of their patients, but this may not be
622 realistic for many practices in the short term.

623
624 Finally, patient portal and e-mail capabilities are not always functionalities required
625 or supported by an EHR system today. Therefore, the measure may create additional
626 burden in time and materials for providers. Many of the technologies that support
627 this capability sit outside of the EHR.

628
629 Improve Care Coordination

630 Department and CMS Requirement as identified in the NPRM

631 Objective: Capability to exchange key clinical information (for example,
632 problem list, medication list, allergies, diagnostic test results),
633 among providers of care and patient authorized entities
634 electronically.
635 Measure: Performed at least one test of certified EHR technology's capacity
636 to electronically exchange key clinical information

637
638 HIMSS Observation on Improved Care Coordination:
639 HIMSS observes that the Interim Final Rule on Standards, Specification
640 Requirements, and Certification Criteria has eliminated a requirement for data
641 transport standards. All that is required is generating either a CCD or CCR, and it
642 needs to receive both. Given the importance of structured data and the focus on a
643 single test, the required test should be done using structured data per allowable
644 standards for patient summary (e.g., CCR or CCD or final standards). In addition, we
645 suggest that the Department and CMS clarify that this test should use standards-
646 based interoperability methods in order to be successful.

647
648 HIMSS observes that personal health record systems are a non-certified technology
649 that is growing in use -- as sponsored by providers via PHRs linked to their EHR,

650 from independent PHRs from vendors like Microsoft, WebMD or Google, and from
651 payers via PHRs linked to their care management applications. It is important to note
652 that a PHR that has been populated with data from an EHR can be a very effective
653 way to support the exchange of key clinical information among providers of care and
654 patient authorized entities. The Department and CMS should consider PHR systems
655 as a means for an EHR that is sending clinical information to a PHR to be qualified
656 for Improving Care Coordination”.

657

658 Medication Reconciliation

659 Department and CMS Requirement as identified in the NPRM

660 Objective: Perform medication reconciliation at relevant encounters and each
661 transition of care

662 Measure: Perform medication reconciliation for at least 80% of relevant
663 encounters and transitions of care

664

665 HIMSS Observation on Medication Reconciliation:

666 HIMSS suggests lowering the threshold for Stage I with a maturation process and
667 threshold. In addition, our members are concerned that the healthcare community
668 needs further guidance on these requirements, including guidelines for exactly what
669 is required for reconciliation. Finally, as with the other measures, this should be
670 substantially reduced below 80%.

671

672 Communicate with Public Health Agencies

673 HIMSS supports the integration of public health data into mainstream EHR solutions.
674 HIMSS supports the Project Public Health IT program, which serves to educate the
675 public health community on the nuances of the public health community’s needs. It is
676 with this spirit that we strongly encourage the Department and CMS to engage in an
677 active data collection program rather than relying on post-event collection, and to clarify
678 the collection requirements and mode of transmittal to the public health departments.

679

680 To that point, HIMSS has been working with the Joint Public Health Informatics Task
681 Force on reviewing the MU requirements for communicating with Public Health
682 Agencies. As a result, we recommend the following:

683

- 684 1. Requiring functionality: As demonstrating the ability of the EHR to transmit
685 standardized data to Public Health agencies is a requirement of the certification
686 criteria, testing the functionality within the EHR certification process should not
687 await the particular local health agency to have receiving systems in place.
- 688 2. Receiving reports: More attention needs to be devoted to making sure that each
689 public health agency has the resources to be ready – to ensure that “a receptor
690 system is operational”.
- 691 3. Data Source Reminders: Electronic laboratory reporting requires the sending of
692 identified results (diagnostic of a disease) from hospital laboratories. Because of
693 the difficulty of parsing and distinguishing reportable/non-reportable results once

694 resident in many EHRs, such data is typically not sent from the EHR, or from
695 clinical providers. HIMSS suggests a possible solution is for the hospital
696 laboratory information systems (or possibly mature HIEs) assemble the data,
697 select out tests and results that are reportable (according to the regulations of the
698 public health jurisdiction), translate them to LOINC and SNOMED codes, and
699 transmit to the public health data center.

700

701 Security Assessments

702 Department and CMS Requirement as identified in the NPRM

703 Objective: Protect Electronic Health information created or maintained by the
704 certified EHR technology through the implementation of
705 appropriate technical capabilities

706 Measure: Conduct or review a security risk analysis per 45 CFR
707 164.308(a)(1) and implant security updates as necessary

708

709 HIMSS Observations on Security Assessments:

710 HIMSS appreciates the necessity of addressing the privacy and security of
711 personal health information in the NPRM. To that end, HIMSS makes the
712 following observations and recommendations:

713

714 First, HIMSS applauds the Department for the 2009 decision to consolidate
715 HIPAA Privacy and Security regulation requirements in the HHS Office of Civil
716 Rights. To improve clarity in the healthcare marketplace, HIMSS recommends
717 that Meaningful Use requirements for privacy and security of personal health data
718 (as outlined in the Stage 1 Objective) should rely on the existing regulations from
719 the Office of Civil Rights. The enforcement and compliance structures are
720 established, and duplication would have the potential of creating confusion and
721 possibly an environment for competing regulations.

722

723 Second, with respect to the risk assessment requirements, HIMSS requests the
724 Department and CMS work to bring clarity to the requirements by identifying
725 such items as what the baseline risk assessment should entail; frequency and
726 scope of the risk assessment; and whether security requirements apply to the
727 provider facility or just the products. Greater specificity in the requirements as
728 well as guidance and resources for small provider practices would be beneficial as
729 well.

730

731 HIMSS relies on members of our Privacy and Security Steering Committee to
732 keep the pulse of security discussions in the healthcare community. HIMSS is
733 receiving informal comments from subject matter experts that the decision to be
734 vague on the risk assessment's requirements is causing many organizations to
735 delay action. In addition, security officers are expressing concern that ill-defined
736 risk assessment requirements are creating anxiety in the healthcare community
737 over the fact that they may not adequately meet the risk assessment requirement.

738

739

740

741

742

743

744

Finally, with respect to potential recommendations for Stage 2 and Stage 3 Privacy and Security Requirements, HIMSS suggests the Department's efforts on reducing duplication and clarifying risk assessment requirements will have a positive impact on ALL stages of MU.

Clinical Quality Measures for Meaningful Use:

745

746

747

748

749

750

To fulfill the ARRA legislative requirement to report quality measures, the NPRM includes a broad set of quality measures to be reported by Eligible Hospitals and Eligible Professionals. We believe the intent of the rule is to advance quality measure reporting by requiring measures which can be HIT enabled as part of the care process, require minimum manual effort, can be reported on electronically at a summary level, lay the groundwork for "measures that matter", and are appropriate to venue and/or specialty.

751

752

753

754

755

There are a number of concerns about the quality measures as laid out in the NPRM in support of this goal. The sheer volume of measures, coupled with the fact that not all of the measures have been adequately defined or tested, and that some required data is not readily available in the EHR, make the current measure sets unable to meet the desired goals within the current timeframes. Specific issues include:

756

757

758

759

760

761

762

763

764

765

766

767

768

769

770

771

772

1. There is not yet an evidence base for many of these measures in practice, demonstrating that the right data can be captured as a byproduct of the patient care workflow. In addition, the process by which measures are reported electronically from EHRs is immature for ambulatory EHRs and lags even further behind for hospital EHRs.
2. Within many EHR systems, the data (in the required standard/terminology) necessary to calculate many of the measures is not available, either because the function is not automated or the data necessary must have manual interpretation to calculate the value.
3. The number of measures is well beyond what can be captured and reported on electronically in the available timeframe. Typically, in a hospital, the process to define how to capture a measure electronically takes about three months. There are 43 hospital measures. In addition, there is overlap of measures captured in other Quality Measure reporting programs; reporting among programs need to be aligned.
4. The measures identified for Eligible Professionals do not authentically reflect how all patients are cared for by each specialty. Therefore, to capture these values and report on them will require nonproductive work by some specialists.

773

774

We support the overall goals and intent of the program, and with that intent in mind we make the following recommendations to address these issues:

775

776

777

778 **Recommendation #1 – Eliminate Core Measure Set for Eligible Professionals:**

779

780 For Eligible Professionals, eliminate the core measure set recommended as mandatory
781 from Table 4 of the Proposed Rule, and pursue measures that are a good fit for each
782 specialty. Physicians in general should be required to meet 3-5 measures; all measures
783 should, where clinically appropriate, include the ability to document patients as
784 exceptions where the measure--i.e., recommended care--is not appropriate for the patient,
785 due to medical, patient, or system reasons.

786

787 **Recommendation #2 – Include a small number of measures which have been**
788 **adequately vetted to ensure they can be captured and reported on through the**
789 **EHR:**

790

791 Where possible, it is desirable that measures should align with other CMS quality
792 reporting programs such as: the PQRI, the RHQDAPU, Outpatient Core measures and the
793 ERSD QIP initiatives.

794

795 When selecting the 3-5 measures for hospitals and for EPs, the following should be
796 considered in adding value to the process:

797

- All data elements required for the measure are available from the EHR and should not require manual processes to determine the data or require data from other systems within the hospital, or even from outside of the hospital.
- Data elements required for the measure, including reasons for exceptions where applicable, can be captured in the EHR as part of the care process.
- The appropriate standardized terminology should be used for data elements required for the measures.

798

799

800

801

802

803

804

805

806 **Recommendation #3 – Implement an aggressive Quality Measures Testing Program**
807 **which ensures measures have been adequately specified and tested before requiring**
808 **them for Meaningful Use:**

809

810 Measures should be appropriately specified within a timeframe that will allow for testing
811 and incorporation by vendors into the EHR.

812

813 Measures required for meaningful use should be adequately tested. Testing should
814 include validation that the data elements are defined consistently, can be captured by the
815 EHR as part of the care process, and are coded in the required terminologies/standards (as
816 per the requirements of Stage 1).

817

818 CMS should implement a quality measure testing program (to ensure feasibility and
819 reliability of the quality measure). The testing program should include all quality
820 measures for both EPs and EHs and should test the EHR measure specifications and
821 should comply with NQF post testing review criteria.

822

823 **Recommendation #4 – Align current Quality Measure Reporting programs with**
824 **new requirements to avoid duplication:**
825

826 Clarify alignment of quality measure reporting requirements for providers participating in
827 multiple CMS quality programs to ensure there is no undue burden and reporting
828 duplication. If reporting quality measures manually, EPs and EHs will still have to report
829 manually, since they are not going through an EHR. But if reporting quality measures on
830 MU through an EHR, then they will not have to report twice. Provide clarification, to
831 increase awareness, to avoid confusion.

832
833 **Recommendation #5 – Limited reporting on quality measures in 2011**
834

835 For Stage 1, we recommend that EPs and EHs be asked to report on 3-5 measures. EPs
836 and EHs would be required to ensure that all data necessary to calculate the measures be
837 documented in the EHR in a standardized way using appropriate code sets where
838 available.

839
840 To allow sufficient time for the other quality measures to be tested, and to allow the
841 testing mechanism to mature, we agree with CMS that direct reporting from EHRs be
842 delayed until 2012 if necessary, or that reporting beyond the initial 3-5 measures per EP
843 or EH also be delayed until Stage 2.

844
845 In the event the Department and CMS continue with the approach to Quality Metrics
846 identified in the NPRM, HIMSS members suggest the following:

- 847 ▪ Consider changing the blood pressure in control level to <130/80 mmHg in lieu
848 of 140/80 mmHG.
- 849 ▪ Consider inserting the option “or documented contraindication or patient
850 declined” associated with appropriate measures
- 851 ▪ Consider expanding the measures required for pediatrics to include fulfilling a
852 need to provide more focus on childhood diseases that require hospitalization
853 such as asthma, developmental issues and weight-based medication dosage safety
854 issues.

855
856 **Health Information Exchange (HIE):**

857 HIMSS supports the government’s intent to accelerate the use of HIE as capabilities
858 increase after Stage 1, and also suggest that the government place more of an emphasis
859 on standards-based HIE in the meaningful use requirements.
860

861 **Economic Impact Analysis:**

862 **Time Requirements and Cost Requirements**
863

864 CMS presents an extensive analysis of information collection requirements (ICR) starting
865 on page 1948. We believe many of the ICR costs are under-estimated. For example:

866

- 867 ▪ The overall 0.5 hours estimated burden, which is inclusive of a large number of
868 meaningful use criteria, seems very low. Even if much of this information can be
869 computed using EHR technology, this computation may be complicated by any
870 modular approach to EHR functionality. Given the number of numerators and
871 denominators that require manual effort or other processes, and the substantial
872 compliance implications of these measures as well as the likely need to internally
873 validate them, we suggest that 0.5 hours is much too low.
- 874 ▪ The 0.5 hour estimate for quality reporting seems very low, especially given the large
875 number of measures for hospitals, the need to ensure that measures are relevant for
876 the hospital populations and the effort to ensure that exclusions are appropriately
877 captured.
- 878 ▪ The estimate of one hour to manually compute the denominator for CPOE use (and
879 for e-prescribing for EPs) seems exceptionally low, especially given the various types
880 of orders that must be considered. Our customers have identified the issue of CPOE
881 denominator measurement as a major anticipated burden.
- 882 ▪ The ICRs address both reporting burdens and capital requirements, they do not
883 address the changes that will be needed to comply with the meaningful use
884 requirements (e.g., the process changes needed to implement CPOE or an automated
885 problem list).
- 886 ▪ Although we very much agree with the Department and CMS that the benefits of
887 EHR use and meaningful use will outweigh the costs, we do think that the discussion
888 in this section and the Regulatory Impact Analysis starting on page 1972 does not
889 give sufficient weight to the initial costs that could offset anticipated incentive
890 impacts, including concerns associated with the likely cumulative impact of reporting
891 and compliance for the very large number of HIT and quality measures.
- 892 ▪ Finally, many of the capital costs seem low for hospitals, and may not fully capture
893 the additional costs associated with acquiring and integrating across multiple EHR
894 modules.

895

896 **Liability Associated with Attestation**

897 The Department and CMS have indicated that attestation will be required for most of the
898 meaningful use requirements in 2011 because it does not expect to be able to receive the
899 information electronically until 2012. Given the complexity of the NPRM requirements
900 and its interaction with the IFR, EPs and EHs are concerned about their possible legal
901 liability for making a false claim if it later turns out that their interpretation of the
902 meaningful use requirements was not correct or the computations of the required
903 percentages did not properly account for all activity that occurred outside the electronic
904 system. Physicians in solo and small group practices have particular concerns due to the
905 small size of their administrative staff.

906

907 Several approaches could be suggested to reduce the exposure of EPs and EHs with
908 respect to these complicated criteria. One overall comment is simply to reduce the
909 number of criteria, the percentages required and the number of clinical quality measures
910 listed on Table 3 of the Proposed Rule.

911

912 In addition, the following could be proposed to balance the government’s need to assure
913 that incentive funds are only made available to EHs and EPs who are making a good faith
914 effort to become meaningful users and the need to provide incentives that will actually
915 result in increased adoption: If a good faith error resulted from a conflicting
916 interpretation of the requirements or a clerical error in determining the number of non-
917 electronic activities, the only obligation of the EH or EP should be to repay the amount of
918 the incentive payment for the payment year in question. Many EP’s are very concerned
919 that they will be liable for unintended implications to creating fraud if the EHR systems
920 do not operate as guaranteed.

921

922 EH and EP should not be liable or have to repay incentives if the EHR vendor selling a
923 certified EHR is later found not to have satisfied the requirements.

924

925 **Areas of Additional Focus:**

926 In reviewing the NPRM, HIMSS members have identified other areas requiring
927 comment, including force majeure and related exceptions; lead time for change and
928 preparing for Stage 2 NPRM; clarification on the certification requirements for support
929 technologies; attestation and associated risk; provider education and training; public
930 health; and Medicare Claims appeals.

931

932 **Force majeure and related exceptions**

933

934 Adequate disaster recovery plans and backup power are required by the HIPAA Security
935 Rule as well as licensing and accreditation standards. However, emergencies and other
936 uncontrollable events are likely to make systems unavailable for hospitals and physicians
937 at some point in time. In addition, downtime may be necessary in order to perform
938 routine maintenance and to implement system upgrades or entire new systems.

939

940 HIMSS notes that system upgrades are likely to be necessary to implement technology to
941 satisfy Stages 2 and 3 of the meaningful use criteria so this issue will be faced by the vast
942 majority of those trying to establish meaningful use. From a patient safety perspective, it
943 is important to adequately test new systems and upgrades before they are used in a live
944 environment and to quickly revert to a less automated workflow if there are questions of
945 clinical quality, data integrity or possible security breaches with the electronic system.

946

947 HIMSS is concerned that the elements of meaningful use that require a percentage
948 threshold for use of a technology or a percentage of physician services outside of a
949 hospital setting need to have exceptions for these situations. For example, appropriate
950 exceptions should help reduce the risk that IT staff fails to quickly terminate use of a
951 malfunctioning CPOE system or an unsecured Internet connection due to concerns about
952 the resulting downtime that could cause the 80% CPOE standard for physicians to be
953 missed. In addition, physicians that practice in both the hospital and non-hospital settings
954 should not lose their incentives if they volunteer in a hospital ED during an emergency

955 even though such activities might push them into the “hospital-based” category under the
956 proposed rule.

957

958 It is impossible to predict every situation for which an exception will be appropriate so it
959 should be drafted broadly and providers should not be liable if they make a good faith
960 effort to qualify for the specific standards set forth in the rule. At a minimum, the
961 exception should include the following:

962

963 ▪ Orders, prescriptions and other activities that are not conducted electronically as a
964 result of a force majeure event should be excluded from denominators and other
965 requirements of meaningful use. “Force majeure” or “Act of God” is often
966 defined as any event that the affected party cannot reasonably control. It should
967 include as examples fires, floods, extreme weather conditions, epidemics, riots,
968 civil unrest, terrorist attack, war, operation of private facilities by government
969 entities in emergency situations, acts of a public enemy, civil or military
970 authority, strikes, lockouts, unavailability of third party services such as Internet
971 connectivity, and shortages or power interruptions that exceed reasonable backup
972 power capability.

973 ▪ Service by physicians at a hospital in emergency situations should not be counted
974 in determining whether the physician is “hospital based.” An emergency would
975 include shortages of hospital personnel due to any force majeure event.

976 ▪ From the hospital’s perspective, if it needs to use the services of physicians,
977 nurses or others who are not trained on its EHR during an emergency, the non-
978 electronic orders, prescriptions and other activities of those temporary personnel
979 should not be counted.

980 ▪ Orders, prescriptions and other activities that occur during planned or emergency
981 system downtime to address technical or clinical issues with the system and
982 connections to the Internet should not be counted in the denominator when
983 computing percentages or otherwise be considered when determining if an
984 element of meaningful use has been satisfied. The downtime would include time
985 spent testing current or new functionality and downtime required for
986 implementation of upgrades or new systems or functionality.

987

988 Finally, HIMSS suggests this exception should be drafted broadly enough to apply to an
989 eligible hospital or eligible professional that is indirectly affected by a force majeure
990 event at another location. For example, a fire at hospital/practice A that results in
991 patients, nurses and physicians being relocated to hospital/practice B which uses an EHR
992 on which the hospital/practice A personnel have not been trained should be considered a
993 force majeure event with respect to both hospitals.

994

995 **Lead Times for Change: Timing of Stage 2 NPRM**

996

997 The NPRM proposes updating the meaningful use criteria on a biennial basis, with the
998 Stage 2 criteria proposed by the end of 2011 and the Stage 3 definition proposed by the
999 end of 2013.

1000

1001 The overall process the healthcare community has been following for the last 12 months,
1002 which defines the requirements for meaningful use and related information, and as laid
1003 out for the future in the regulation, provides for too much uncertainty for healthcare
1004 providers and technology vendors. For example, eligible hospitals and professionals may
1005 be faced with patient safety concerns that arise from the volume of requirements for
1006 implementation and insufficient lead-time for complete testing of products and
1007 workflows.

1008 For example, the timeframes from when providers and vendors receive final requirements
1009 for Stage 1 and when they need to be generally available to customers is inadequate.
1010 Final requirements will not be available until approximately May 2010 or even later. For
1011 hospitals who want to pursue 2011 incentives, the software needs to be generally
1012 available, then implemented in the hospital as early as October of 2010. This timeline
1013 does not allow adequate time for software development, thorough quality assurance
1014 testing, general availability and implementation in practices and hospitals.

1015 In addition, the timeframes for the NPRM in Stage 2 and Stage 3 of meaningful use
1016 appear to repeat the same short timeframes. Implementing new meaningful use
1017 applications or functions that may be identified prior to the start of these stages may limit
1018 the number and complexity of software changes available to eligible hospital and
1019 professional sites.

1020

1021 To address this issue, HIMSS recommends the development of a multi-stage time frame
1022 to allow for vendors and providers to plan for and implement requirements. For
1023 example, prior to ARRA, the federal government and healthcare community worked
1024 together to develop and implement a road-mapping process. The roadmap included an
1025 18-month advance notice on the intent to certify a specific function, using already
1026 clearly-defined and federally-recognized specifications for interoperability (from HITSP).
1027 This approach provided continuity in direction, which allowed vendors and providers to
1028 be forward-looking and prepare for required functions and implementations of those
1029 functions within more realistic timeframes.

1030 Accomplishing the 18-month lead-time will require an NPRM for Stage 2 by the end of
1031 2010. HIMSS recognizes this timeframe might not allow for adequate understanding and
1032 experience on Stage 1, which should directly contribute to the requirements for Stage 2.

1033 Therefore, we recommend the following:

- 1034
- 1035 ■ The NPRM for Stage 2 be available by the end of 2010 and the final rule by April
1036 by April 2013 at the latest.
 - 1037 ■ The final rule for each stage should identify a clear pathway for content
1038 requirements for the next stage. This will ensure appropriate testing and
1039 acceptance of the MU criteria as supported by the EHR, by EPs and EHs.

- 1040 ▪ The 90–day reporting period should be in effect for the first reporting years for
1041 Stage 2 and Stage 3. The shorter reporting period allows providers to have a
1042 chance to learn the requirements for each subsequent stage and have time to ramp
1043 up to meet the new requirements.

1044

Clarify that non-certified technology can be used to help meet a MU criterion

1045

1046

1047

1048

1049

1050

1051

1052

1053

1054

1055

1056

1057

1058

1059

The Department and CMS propose to use the certification definitions in the companion Interim Final Rule on standards and certification criteria. This IFR sets out a modular approach to certification. The IFR defines a module as “any service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary.” The IFR goes on to indicate that it is the responsibility of the eligible professional or eligible hospital to perform due diligence to ensure that the selected certified EHR modules are capable of working together to support achievement of meaningful use, and that EPs and EHs should take care to ensure that the certified EHR modules they select are interoperable and can properly perform in their expected operational environment. This is a big undertaking for EPs and EHs regardless of size and encompasses organizational change and support capabilities to achieve required performance.

1060

1061

1062

1063

1064

1065

HIMSS agrees with the concerns raised by ONC regarding the need for disparate modules to be able to work together effectively to support meaningful use and to achieve the functional equivalence of a Complete EHR, as such was likely envisioned by the Congress. We also believe that providers need additional guidance and support on how they are to implement the modular approach to certified EHR technology.

1066

1067

1068

1069

1070

1071

Therefore, HIMSS recommends that the Department and CMS recognize that hospitals and physicians use many systems to support their efforts (e.g. additional software such as report-writers) to meet their clinical and quality goals. These systems should not be precluded from supporting efforts to achieve meaningful use and should not require separate vendor certification or require the provider to apply for Site Certification.

1072

1073

1074

1075

1076

1077

1078

1079

1080

1081

1082

1083

Support the recommendation in the NPRM that providers who are deemed Medicare Meaningful Users should also be deemed Medicaid Meaningful Users

Hospitals can qualify for both Medicare and Medicaid incentives. The Department and CMS propose that if a hospital is deemed a Meaningful User for Medicare, then it is automatically deemed as a Medicaid Meaningful User. HIMSS supports this proposal as the current set of requirements for Medicare is substantial. Adding any additional Medicaid specific measures will add too much burden to an already high bar for providers. HIMSS agrees with the NPRM provision that hospitals that are Medicare meaningful users should be deemed to meet Medicaid meaningful use and ask for clarification that states cannot impose additional requirements that would negate such deeming.

1084 Unlike eligible hospitals that are deemed to be meaningful users under Medicaid by
1085 meeting the Medicare criteria, eligible professionals seeking Medicaid incentive
1086 payments must meet the Medicare “floor” for meaningful use and any additional state
1087 requirements that CMS approves. CMS would restrict states from adding required
1088 functionality to the EHR, but allow states to add additional objectives for eligible
1089 professionals and hospitals or measure their achievement in a different way as early
1090 as Stage 1. We are concerned that giving states this latitude presents several
1091 problems, most notably the timeframes for achieving meaningful use. First, states
1092 may delay their rollout for Medicaid EHR incentive programs to prepare and
1093 negotiate amendments to the definition of meaningful use with CMS. States may
1094 select objectives for which the vendor community is not ready, leaving EPs with the
1095 need to customize their software once they learn of these special objectives. Further,
1096 this additional layer of requirements will be imposed on a provider group already
1097 burdened with many administrative and operational challenges to adopt and achieve
1098 meaningful use.
1099

1100 **Impact of Meaningful Use on hospitals that are opening in 2010 or later**

1101 HIMSS encourages the Department and CMS to consider the unique operational
1102 challenges facing eligible hospitals that will be opening in 2010 or later. HIMSS
1103 encourages the Department and CMS to provide a specific five-year timeline that will
1104 afford these facilities some flexibility in achieving Stage 2 and 3 without the automatic
1105 penalties that will occur after 2015 for the Medicare EHR Incentive Payment Program.
1106

1107 **Risk to self-attestation and risk to practices with regard to the False Claims Act**

1108 Most eligible providers will be able to accomplish in Stage 1 in good faith effort. We
1109 would like to see a reasonable statement for physicians to incorporate an exclusion clause
1110 for exceptions of special circumstances for system upgrades, system downtime, public
1111 health emergencies and emergency preparedness situations with regard to the CPOE
1112 requirement. Attestations should be based on good faith belief, that the hospital or EP
1113 used, or used a service that used, certified EHR technology, along with a general
1114 description of the technology used.
1115

1116 **Impact on Training**

1117 A heightened focus on the education and training of clinicians in the practice of informatics
1118 will be crucial to successfully achieving these goals. Of particular note is the need to
1119 clarify the role of physician and clinician training programs and their associated faculty
1120 medical practices. Those clinicians in training and those new to the field should be
1121 prepared to support the effective use of resources for health information technology as an
1122 integral part of their clinic experience in both the acute care and ambulatory care settings.
1123 Informatics competencies and recommendations for practicing clinicians should be
1124 required, including basic computer competencies, information literacy, and information
1125 management. The growing complexity in the healthcare environment mandates new
1126 competencies that, in turn, necessitate new educational strategies and curricular content
1127 to prepare the workforce that can enable a U.S. healthcare system capable of using EHRs
1128 to improve the delivery of healthcare.

1129

1130

1131 **Reconciliation between the Meaningful Use NPRM and the Standards and**
1132 **Certification Criteria Interim Final Rule**

1133 HIMSS has been made aware of several differences between the NPRM and the IFR that
1134 need to be clarified, including a list of information that needs to be provided to patients,
1135 e.g. “access” in ambulatory has “immunizations and procedures” in the IFR and not in the
1136 NPRM. Similarly, tests are defined as “diagnostic tests” in some places and “laboratory
1137 tests” in others.

1138

1139 **Public Health**

1140 HIMSS has established a working relationship with the public health community,
1141 particularly with the Joint Public Health Informatics Task Force, a collaboration between
1142 seven non-profit organizations supporting a public health mission.

1143

1144 As such, HIMSS is supportive of the population health objectives and measures included
1145 in the CMS NPRM. HIMSS believes that the public health reporting requirements strike
1146 the correct balance between advancing the use of data for population health improvement
1147 and recognizing the limitations that exist with the current health information technology
1148 infrastructure.

1149

1150 HIMSS recognizes the infrastructure necessary to support the electronic exchange of
1151 information with public health departments is still to be developed in many parts of the
1152 country. This is particularly true for local health departments, which have varying
1153 capacity to send and receive data electronically. This situation is likely to be slow to
1154 change given the dire budget situation in which local health departments find
1155 themselves. There is a risk that one of the five key goals identified by ONC and CMS for
1156 the use of EHR, improving population and public health, will not be achieved without
1157 additional investment. HIMSS supports efforts to find funding mechanisms for state and
1158 local health EMR implementation.

1159

1160 HIMSS would like to note that all local health departments provide some primary care
1161 services, such as maternal and child health services, tuberculosis case management,
1162 immunizations, refugee health, and sexually transmitted disease clinics. These services,
1163 while not comprehensive primary care, all generate large amounts of data that form an
1164 important part of a patient’s record. As it currently stands, there are no financial
1165 incentives for local health departments to develop systems that will feed into the network
1166 of EHRs and HIEs being promoted through HITECH. Without a flexible interpretation of
1167 “meaningful use” or a separate system of financial incentives, this information will
1168 remain disconnected from other patient data and an opportunity to improve the quality of
1169 care will be missed.

1170

1171 Both lab and immunization reporting are key areas not only for population health
1172 improvement but also to support improvements in clinical care outcomes, coordination of
1173 care and other areas of interest to CMS and ONC. The H1N1 pandemic has shown the

1174 utility of real-time baseline and syndromic surveillance information to support public
1175 health and clinical decision making.

1176

1177 **Allow Medicare Appeals similar to the Medicaid Appeals Process**

1178 HIMSS requests that the Department and CMS consider a review process to ensure that
1179 its Medicare contractors make fair and accurate decisions on EH and EP incentive
1180 payments. The NPRM §495.370 requires states to have in place an appeals process for
1181 Medicaid providers receiving incorrect incentive payments, incentive payment amounts,
1182 or an incorrect determination of eligibility (including measuring patient volume;
1183 demonstrating meaningful use of, or the efforts to adopt, implement, or upgrade to,
1184 certified EHR technology; whether the professional is hospital-based; whether the
1185 professional is practicing predominantly in an FQHC or RHC; whether the hospital
1186 qualifies as an acute care or children’s hospital; or whether the provider is already
1187 participating in the Medicare incentive program and therefore ineligible under the
1188 Medicaid incentive program.) Medicaid providers have the opportunity to challenge the
1189 determination by submitting documents or data or both, consistent with the state’s
1190 administrative procedure act (APA).

1191 Although ARRA limits administrative or judicial review of the methodology and
1192 standards for determining payment amounts and reporting periods, it is critical that CMS
1193 adopt a similar process for Medicare providers who believe their incentive payments have
1194 not properly been reviewed. CMS contractors may make mistakes in processing MU
1195 determinations, and having an opportunity to correct the record, ensure it is complete and
1196 supplement it as necessary is important to ensure that eligible professionals and hospitals
1197 receive due process and develop trust in the system. Providing a limited review process
1198 for Medicare that mirrors the Medicaid process and is consistent with the federal APA
1199 would be an appropriate solution.

1200

1201 Conclusion:

1202 The American Recovery and Reinvestment Act has created many challenges and
1203 opportunities for the federal government and the healthcare community. We appreciate
1204 your effort to engage healthcare stakeholders in reviewing the guidance document, and
1205 look forward to future dialogue with HHS on this important issue.

1206

1207 HIMSS has received anecdotal evidence that the healthcare community is spending a
1208 considerable amount of time learning how to become meaningful users. HIMSS has
1209 devoted resources, including successful webinars and information on the HIMSS website,
1210 to ensure our collective expertise is utilized to ensure fellow members and industry
1211 colleagues are able to maximize their preparedness for meaningful use. HIMSS
1212 leverages these resources, including the Return on Investment Information from Davies
1213 Award Recipients, to assist in provider education. We stand ready to work with the
1214 Department and CMS to ensure our community members are ready for the start of the
1215 Medicare and Medicaid EHR Incentive Program.

himss Comments on Medicare and Medicaid Programs; Electronic Health
Record Incentive Program [CMS – 0033—P; RIN 0938 – AP78]

1216 Finally, on behalf of entire Society, we appreciate the opportunity to engage in a healthy
1217 dialogue with the Department and CMS on this critical proposed rule. We are prepared
1218 to discuss these observations and recommendations with the government as you review
1219 the comments and move forward on the release of the Final Rule later this year. If you
1220 have any questions, please feel free to contact our staff point of contact,
1221 Mr. Thomas M. Leary, Sr. Director for Federal Affairs.

1222
1223 Sincerely,
1224



1225
1226
1227 Barry P. Chaiken, MD, FHIMSS
1228 Chair, HIMSS Board of Directors
1229 CMO, DocsNetwork, Ltd.
1230 CMO, Imprivata, Inc.



H. Stephen Lieber, CAE
President/CEO
HIMSS