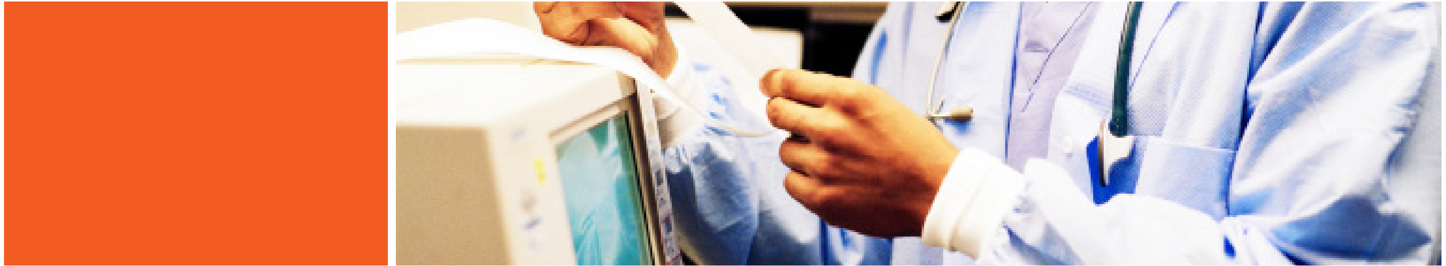
NOVARTIS **OPM**
NEWSLETTER

Quarterly Health Policy Updates for Novartis Oncology Practice Managers

DECEMBER 2010



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Note:
These updates are provided to you as an informational reference as a Novartis Oncology OPM speaker

ICD-10 Coding System in 2013: Prepare for Implementation Now

Starting on October 1, 2013, the International Classification of Diseases, Tenth Revision (ICD-10) coding system must be used as the new standard of medical coding across all healthcare settings in the United States.[1,2]

In particular, this transition will require systems and business adjustments throughout the healthcare industry, impacting all entities and transactions covered by the Health Insurance Portability and Accountability Act (HIPAA).[1,2]

ICD-10 will replace the current coding system, the International Classification of Diseases, Ninth Revision (ICD-9). Developed in the 1970s, the ICD-9 coding system is rapidly becoming obsolete and diminishing in capacity to support today's advanced health information needs.[3]

Adoption of the ICD-10 coding system in the United States marks a significant change, especially considering that it is the only industrial nation which has not yet completed this upgrade. Not only does the ICD-10 adoption enhance medical diagnosis coding, but it is also in alignment with the nationwide goals of moving towards greater use of electronic health records with improved disease tracking and quality monitoring.[3,4]

1. http://www.cms.gov/ICD10/01_Overview.asp
2. http://www.cms.gov/ICD10/05a_ProviderResources.asp
3. http://www.ahima.org/icd10/replaced.aspx
4. http://www.ahima.org/icd10/

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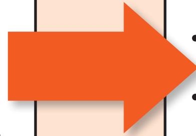
ICD-9 coding system is outdated because it:

- Lacks sufficient medical specificity and detail
- Has a limited structural design that cannot keep up with the current advances in medical knowledge and technology
- Does not support the nationwide transition to providing quality data as well as the interoperability of health data exchange
- Is a barrier to true comparisons of medical cost and clinical outcomes, including on a global level (i.e. global data sharing for public health research)



Implementation of ICD-10 coding is expected to advance healthcare in:

- Quality measurement
- Public health
- Research
- Organizational monitoring and performance
- Reimbursement

ICD-9	ICD-10
• Codes contain 3 to 5 digits • Contains 13,000 diagnosis codes • Contains 3,000 procedure codes	• Codes contain 3 to 7 digits • Contains 68,000 diagnoses codes • Contains 87,000 procedure codes

While the officially regulated conversion date to adopting ICD-10 is about two years away, the compliance timeline is firm and not subject to change. Given this, it is important for oncology practices to prepare for the transition to ICD-10 in advance to avoid any potential reimbursement issues.[2]

In general, with the replacement of ICD-9 coding, providers will need to learn new reporting systems for diagnosis and procedures, and, payers will be adjusting coverage policies, claims processing utilization management, and other operational systems.

In addition, starting on January 1, 2012, standards for electronic healthcare transactions will change to Version 5010 from Version 4010/4010A1, including such functions as claims eligibility inquiries and remittance advice. Version 5010 accommodates the utilization of ICD-10 codes and must be functioning prior to full transition to the updated diagnosis system. Specifically, the transition date to Version 5010 has been planed well in advance of the ICD-10 conversion date to allow for enough time for Version 5010 update and testing. If oncology practices do not implement and utilize Version 5010 by the transition date, delays in reimbursement are likely to occur.[1]

According to the Centers for Medicare and Medicaid Services (CMS), "Preparing for ICD-10 and Version 5010 – including potential updated software installation, staff training, changes to business operations, and workflows, internal and external testing, reprinting of manuals and other materials, and more – will take time..."[1]

An integral component to planning for the ICD-10 transition is to manage limited resources, competing priorities, and inflexible deadlines, which requires oncology practices to take a disciplined, phased, and proactive approach to adopting this new coding system. In particular, with the recent passage of complex legislation, such as healthcare reform and other related regulation, oncology practices should anticipate many workflow changes.[5]

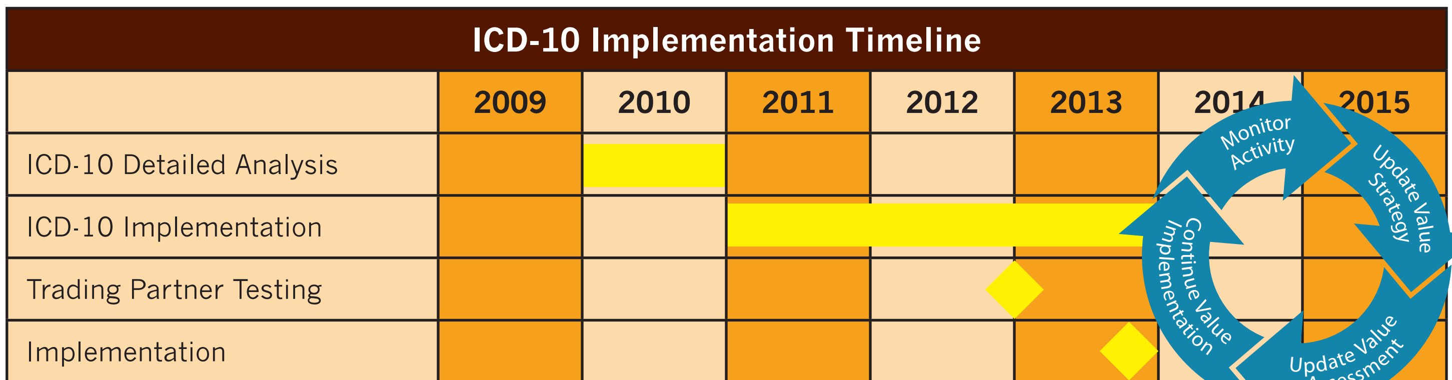
5 Daryl Dickhudt, Paul Steinichen and Jordan Battani. "ICD-10 IMPLEMENTATION: OBJECTS ON THE HORIZON ARE CLOSER THAN YOU THINK" Computer Science Corporation, April 2010.

According to one report, "the sheer magnitude of the business process and technology changes that are required for ICD-10 implementation may be a deterrent to assessment and planning as well."[5] Given all that is going on with the current health policy landscape, it will be important to balance and incorporate ICD-10 implementation with other activities.

In preparation for the implementation and migration plan for ICD-10 coding, oncology practices may want to consider the following overall framework:[2]

- Identify current systems and work needs/processes that use ICD-9 codes, including clinical documentation, encounter forms, superbills, practice management systems, electronic health record systems, contracts, and quality reporting tools
- Communicate with the practice management system vendor about accommodations for both Version 5010 and ICD-10 codes and review contracts for any such updates
- Review the transition plan with all clearing houses, billing services, and payers to discuss their processes for compliance and system testing
- Discuss with payers how the transition to the ICD-10 coding system may impact current contracts
- Identify potential workflow changes as an opportunity to either improve existing or develop new processes
- Assess training needs for practice staff and research available resources, such as online courses, webinars, or onsite training; professional coders recommend training practice staff at least six months prior to the ICD-10 implementation date of October 1, 2013
- Evaluate and account for budgetary expenses related to the implementation of ICD-10 coding, such as for costs for staff training, resources, and other system needs
- Test transactions with payers and clearinghouses by submitting test claims utilizing ICD-10 codes and Version 5010

Once the implementation deadlines have been met, oncology practices should consider conducting ongoing improvement monitoring.[5]



Source: Daryl Dickhudt, Paul Steinichen and Jordan Battani. "ICD-10 IMPLEMENTATION: OBJECTS ON THE HORIZON ARE CLOSER THAN YOU THINK" Computer Science Corporation, April 2010.

For more information and resources on ICD-10 implementation, please visit: **http://www.cms.gov/ICD10/01_Overview.asp.**

OIG, HHS Review Healthcare Fraud Prevention in Nationwide Summit Series

Earlier this year, in an effort to fight healthcare fraud and promote its prevention, President Obama announced the launch of a nationwide series of regional summits, from Miami, Los Angeles, and Las Vegas, to Detroit, Boston, New York, and Philadelphia.[6]

In July, multiple participants from the federal, state, and local levels, convened the first summit in the series, which was held in Miami and kicked off by Attorney General Eric Holder and United States Department of Health and Human Services (HHS) Secretary Kathleen Sebelius.[6]

According to a news report, Sebelius said, "The days of scamming dollars from our healthcare system are over. Thanks to new tools contained in the Affordable Care Act, we are more prepared than ever to safeguard taxpayer dollars and ensure that the healthcare coverage of our seniors, families, and children is secure. I'm proud of the tremendous success we've had so far, and look forward to continuing this important dialogue at fraud prevention summits across the country."[6]

In particular, the Patient Protection and Affordable Care Act (PPACA), which was signed into law in March 2010, allocates a budget of $350 million to the Health Care Fraud and Abuse Control Account over the next ten years. With a focus on innovative strategies, PPACA provides the authority to put more oversight measures in place, such as sentencing for criminal activity, private insurance fraud, as well as, improved patient enrollment screenings, and, better data-sharing across government entities. In addition, the Health Care Fraud Prevention and Enforcement Action Team (HEAT), an intra-gency government task force, which was created in 2009, continues to address fraud, waste, and abuse in healthcare. Specifically, this task force has been focusing on cities were fraudulent activity has been uncovered the most, including Los Angeles, Houston, Detroit, Brooklyn, Baton Rouge, and Tampa.[6]

According to the Office of Inspector General (OIG) and HHS, healthcare providers, including oncology practice managers, can take the following steps to avoid or minimize allegations of healthcare fraud:[7]

- Understand and comply with criminal, civil, and administrative laws
- Develop an organizational culture or program of legal compliance and integrity
- Self-report problems to the government and become a partner to fighting healthcare fraud
- Sustain quality of patient care

With the growing emphasis from the federal government on developing programs and forums to address healthcare fraud detection and promote its prevention, it is important for oncology practices to understand and follow such guidance and policies.

6 http://www.fiercehealthcare.com/press-releases/vattorney-general-holder-and-secretary-sebelius-kick-first-regional-health-care-fraud
7 http://www.fiercehealthfinance.com/story/oig-big-wigs-review-fraud-prevention-basics/2010-07-21?utm_medium=nl&utm_source=internal

CMS Provides Additional Guidance on Closing the Medicare Part D Coverage Gap in 2011

On September 10, 2010, CMS released additional guidance regarding the closing of the Medicare Part D coverage gap to Part D sponsors with more details on its upcoming implementation. Specifically, the memorandum provides guidance in the following areas:[8]

Enhanced alternative benefit designs without an initial coverage limit[8]

For purposes of determining when the Medicare Part D coverage gap begins, Part D plans shall apply their plan-specific initial coverage limit (ICL) under basic alternative, actuarially equivalent, or enhanced alternative Part D benefit designs. Therefore, if a Part D plan increases it's ICL by $500, the discounts could not begin until the individual exceeds the plan's ICL. If there is no ICL, the defined standard ICL must be used to identify coverage gap claims for drugs that are subject to discount.

Non-calendar year Employer Group Waiver Plans (EGWPs)[8]

Non-calendar year EGWPs must implement coverage gap changes on a calendar year basis. Applicable beneficiaries that have reached the coverage gap during their non-calendar plan year will be eligible for coverage gap discounts beginning January 1, 2011 based upon their existing non-calendar year accumulated drug costs for applicable (i.e. brand) drugs. Accumulated drug costs will reset at the beginning of the next non-calendar plan year.

Covered Medicare Part D drugs that are not applicable drugs under the Medicare Coverage Gap Discount Program (CGDP)[8]

Medicare Part D drugs approved under an abbreviated new drug application are not considered applicable drugs. Furthermore, all categories of Part D drugs that are not applicable drugs will be subject to "generic" coverage gap cost-sharing in 2011 (e.g. medical supplies associated with the delivery of insulin, Part D compounds). CMS does not believe that many of the older prescription drugs currently on the market meet the definition of a Part D drug. Therefore, Part D sponsors should make careful determinations to cover any such drugs.

Medicare Part D vaccine administration fees[8]

In a previous guidance issued in May 2010, CMS clarified that vaccine administration fees would be included in the negotiated price for determining the applicable discount. Upon further consideration, CMS determined that vaccine administration fees are analogous to dispensing fees and must be excluded from the definition of negotiated price for determining the applicable discount. If the vaccine administration fee is billed separately from the vaccine in the coverage gap, it is subject to neither a discount under the CGDP nor "generic" coverage gap cost-sharing.

8 Cynthia G. Tudor, Ph.D., Cheri Rice. "Additional Guidance concerning Closing the Coverage Gap in 2011" CMS, September 2010.

Medicare Part D compounds[8]

In the same previous guidance issued in May 2010, CMS had also stated that Medicare Part D sponsors shall provide a discount on Part D compounds in certain scenarios. Upon further consideration, CMS determined that Part D compounds are not applicable drugs for the CGDP. While Part D sponsors can cover compounds with at least one Part D drug ingredient, CMS believes that the applicable drug determination must be made with respect to the compound as a whole. Part D sponsors must apply the "generic" gap cost-sharing to the Part D drug components of all Part D compounds.

Brand-only deductibles[8]

With the implementation of the CGDP, Medicare Part D deductibles will cease to apply once a beneficiary's total gross covered drug costs exceed the ICL. Beneficiaries enrolled in a Part D plan with a brand-only deductible will be eligible for a coverage gap discount on applicable (i.e. brand) drugs once the beneficiary's total gross covered drug costs exceed the ICL, even if the beneficiary has not satisfied the deductible.

With the phase out of the Medicare Part D coverage gap, it is critical for oncology practices to continue tracking any additional information that CMS issues in the form of guidance and understand these changes as related to patient care.

Understanding Accountable Care Organizations (ACOs) as New Coordinated Care Models

Healthcare reform authorizes the implementation and use of accountable care organizations (ACOs), which are networks of doctors, hospitals, and other providers that work together to improve the quality and coordination of health care services for a defined patient population.[9,10]

Medicare will formally begin using ACOs in 2012, and providers are already developing models for the private insurance market. For now, ACOs are still being shaped by CMS and federal regulators. Many gray areas cushion the parameters of the law to prevent hindering innovation for the first few providers to develop ACO models. The quality benchmarks are also still being developed by CMS, federal regulators, and the initial groups of providers designing ACO models.[9]

Select features of these new models of coordinated care include performance measurements, and "invisible enrollment."

Invisible enrollment refers to patients being assigned to an ACO of which his or her provider participates. This assignment to an ACO would allow closer coordination or care, especially if a hospital is involved.

9 http://www.npr.org/templates/story/story.php?storyId=130494923
10 http://www.rwjf.org/coverage/product.jsp?id=66449&cid=XEM_910232

Performance measurement is a key component in the development of ACO models, whereby payers collect data on elements such as utilization for the ACO population regarding quality of care and overall population health. Based on certain quality requirements, providers could be required to meet minimum standards, which would encourage continuous improvement.

As popular as the idea of ACOs have become within the healthcare community, serious challenges are expected to remain after the first few years of implementation. In general, single-physician practices and small groups lack the data systems and health technology needed to form strong ACOs. Many practices and hospital/physician joint-ventures are structured to focus on maximizing the volume of services they provide to patients, as opposed to emphasizing the quality of care. In addition, ACOs may face legal hurdles, such as antitrust laws.

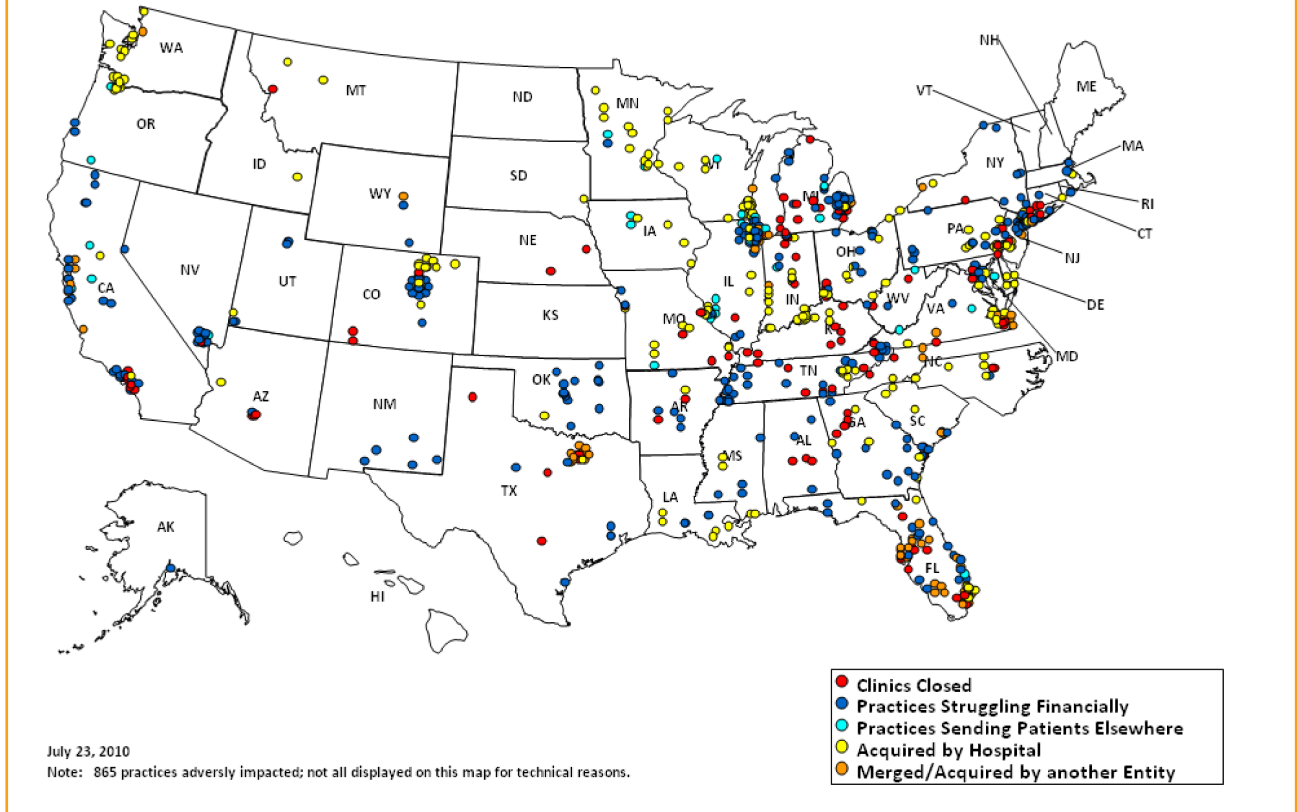
Considering this trend towards adopting models of coordinated care, many healthcare providers are looking to restructure their existing practices and develop new partnerships. High-level coordinated care has been difficult to achieve when hospitals and doctors operate independently, but with both parties being encouraged to collaborate and focus on improving quality of care, ACOs may be equipped to experience success. ACOs will undergo continuous reshaping and restructuring throughout the next few years, but may remain one of the leaders down the path of healthcare reform.

COA Publishes Report on Rise in Community Cancer Closings

Recently, the Community Oncology Alliance (COA) announced that "due to severe year after year cuts to Medicare reimbursement for cancer care, community oncologists around the United States are closing offices at a rate rapidly increasing since January 2010." In particular, COA reports that in the past three years, 166 community cancer clinics have closed, and since the beginning of this year alone, 30 community cancer clinics in 15 states have either closed or are in the process of closing. Nationwide, hundreds of other oncology practices have experienced adverse impacts from declining Medicare reimbursement, including dealing with financial challenges to pay bills, deferring patients with Medicare to other sites of service for therapy, and being acquired by larger hospitals (please see map). [11, 12]

Specifically, with the deferrals to other locations, many patients now face barriers to accessing care in their own communities. Due to the burden of longer travel distances, especially for patients residing in rural areas, routine care may be compromised, including the potential for adverse impact to consistency and quality in treatment.[11]

11 http://www.communityoncology.org/community-cancer-clinic-closings-on-the-rise-2/
12 Community Oncology Cancer Care Practice Impact Report July 2010



Source: Community Oncology Cancer Care Practice Impact Report July 2010.

President of the COA, David Eagle, MD, said "As a practicing oncologist, I am extremely concerned about the impact these closings have on patients. Many are simply falling through the cracks as providers as being forced to cut staff and close clinics, forcing patients to seek treatments outside of their communities."[11]

To track these trends, the COA has developed a database that monitors the adverse impact to community cancer centers as a result of cuts in reimbursement for oncology care.[11]

Additionally, it is anticipated that in the coming years, there will be a decrease in the number of oncologists treating patients and an increase in the number of oncology patients needing care. By 2020, it is estimated that patient visits with oncologists will increase by 48 percent, but that the number of oncologists treating patients is expected to fall short by over 4,000.[11]

Considering this larger picture, coupled with the fact that approximately four out of five cancer patients in the United States are treated in the community oncology practice setting, the role of practice management is more important than ever in sustaining excellence in oncology patient care.[11]

HOT TOPIC

Adopting "Meaningful Use" Standards in EHR Systems May Improve Healthcare Quality, Efficiency, and Patient Safety

Earlier this year, the Department of Health and Human Services (HHS) issued "meaningful use" standards of electronic health records (EHRs), building on the platform for increased health information exchanges, as well as the interoperability of systems. In 2009, the American Recovery and Reinvestment Act (ARRA) and Health Information Technology for Economic and Clinical Health Act (HITECH) were signed into law, which not only support the adoption of EHR systems and meaningful use, but also authorized up to $27 billion in incentive payments for healthcare entities that accurately use this technology per the criteria outlined in the policies.[13]

According to the CMS, the goal is: "…for the definition of meaningful use to be consistent with applicable provisions of Medicare and Medicaid law, while continually advancing the contributions certified EHR technology can make to improving health care quality, efficiency, and patient safety."[14]

In addition, the full adoption of meaningful use in an EHR system, may likely lead to a reduction in errors and increased availability of data and records, as well as use of features such as reminders, alerts, and e-prescribing automation.[15]

Through CMS' Medicare and Medicaid EHR incentive programs, CMS intends to expand the meaningful use of certified EHR technology, and as such, eligible physicians, hospitals, and other healthcare providers have the opportunity to potentially receive additional incentive payments from the government. In order to be eligible, adopted EHR systems must comply with and be certified on specific technical standards.[15]

Overall, the meaningful use objectives are comprised of three main components:[15]

- Use of certified EHR technology in a meaningful matter

- Use of certified EHR technology for electronic exchange of health information to improve healthcare quality

- Use of certified EHR technology to submit clinical quality measures

Per legislation, the roll out of meaningful use will involve three stages, which at current time, only "Stage 1" specifications have been released; the two other stages will be proposed by CMS through future rulemaking processes.

13 http://healthpolicyandreform.nejm.org/?p=3732&query=home/
14 http://www.cms.gov/apps/media/press/factsheet.asp?Counter=3794&intNumPerPage=10
15 http://www.cms.gov/EHRIncentivePrograms/35_Meaningful_Use.asp

Stage 1, which will begin shortly, focuses on the following meaningful use criteria: [14,15]

- Electronically capturing health information in a coded format
- Using that information to track key clinical conditions
- Communicating that information for coordination of care purposes
- Initiating the reporting of clinical quality measures and public health information

More specifically, in Stage 1, meaningful use is comprised of both a core set and a menu set of objectives which are specific to eligible professionals and eligible hospitals.

2010	2011	2012	2013	2014	2015
	Stage 1 EFFECTIVE		Stage 2 ESTABLISHED		Stage 3 ESTABLISHED

For eligible professionals, a total of 25 objectives/measures are available, 20 of which need to be completed in order to qualify for an incentive payment with the specified breakdown of 15 core set objectives and 5 menu set objectives (please see table). [14,15]

For eligible hospitals, a total of 24 objectives/measures are available, with the specified breakdown of 14 core set objectives and 5 menu set objectives (please see table). [14,15]

In the current healthcare environment where health information technology, including meaningful use and EHR, are becoming national standards, it is important for oncology practices to not only be aware of related policies and legislation, but also to put strategic plans and timelines in place to adopt and implement these key tools.

Summary Overview of Meaningful Use Objectives.*	
Objective	Measure
Core set†	
Record patient demographics (sex, race, ethnicity, date of birth, preferred language, and in the case of hospitals, date and preliminary cause of death in the event of mortality)	More than 50% of patients' demographic data recorded as structured data
Record vital signs and chart changes (height, weight, blood pressure, body-mass index, growth charts for children)	More than 50% of patients 2 years of age or older have height, weight, and blood pressure recorded as structured data
Maintain up-to-date problem list of current and active diagnoses	More than 80% of patients have at least one entry recorded as structured data
Maintain active medication list	More than 80% of patients have at least one entry recorded as structured data
Maintain active medication allergy list	More than 80% of patients have at least one entry recorded as structured data
Record smoking status for patients 13 years of age or older	More than 50% of patients 13 years of age or older have smoking status recorded as structured data
For individual professionals, provide patients with clinical summaries for each office visit; for hospitals, provide an electronic copy of hospital discharge instructions on request	Clinical summaries provided to patients for more than 50% of all office visits within 3 business days; more than 50% of all patients who are discharged from the inpatient department or emergency department of an eligible hospital or critical access hospital and who request an electronic copy of their discharge instructions are provided with it
On request, provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies, and for hospitals, discharge summary and procedures)	More than 50% of requesting patients receive electronic copy within 3 business days
Generate and transmit permissible prescriptions electronically (does not apply to hospitals)	More than 40% are transmitted electronically using certified EHR technology
Computer provider order entry (CPOE) for medication orders	More than 30% of patients with at least one medication in their medication list have at least one medication ordered through CPOE
Implement drug–drug and drug–allergy interaction checks	Functionality is enabled for these checks for the entire reporting period
Implement capability to electronically exchange key clinical information among providers and patient-authorized entities	Perform at least one test of EHR's capacity to electronically exchange information
Implement one clinical decision support rule and ability to track compliance with the rule	One clinical decision support rule implemented
Implement systems to protect privacy and security of patient data in the EHR	Conduct or review a security risk analysis, implement security updates as necessary, and correct identified security deficiencies
Report clinical quality measures to CMS or states	For 2011, provide aggregate numerator and denominator through attestation; for 2012, electronically submit measures
Menu set‡	
Implement drug formulary checks	Drug formulary check system is implemented and has access to at least one internal or external drug formulary for the entire reporting period
Incorporate clinical laboratory test results into EHRs as structured data	More than 40% of clinical laboratory test results whose results are in positive/negative or numerical format are incorporated into EHRs as structured data
Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach	Generate at least one listing of patients with a specific condition
Use EHR technology to identify patient-specific education resources and provide those to the patient as appropriate	More than 10% of patients are provided patient-specific education resources
Perform medication reconciliation between care settings	Medication reconciliation is performed for more than 50% of transitions of care

Source: David Blumenthal, M.D., M.P.P., and Marilyn Tavenner, R.N., M.H.A. The "Meaningful Use" Regulation for Electronic Health Records, NEJM | July 13, 2010

Summary Overview of Meaningful Use Objectives (Continued.)	
Provide summary of care record for patients referred or transitioned to another provider or setting	Summary of care record is provided for more than 50% of patient transitions or referrals
Submit electronic immunization data to immunization registries or immunization information systems	Perform at least one test of data submission and follow-up submission (where registries can accept electronic submissions)
Submit electronic syndromic surveillance data to public health agencies	Perform at least one test of data submission and follow-up submission (where public health agencies can accept electronic data)
Additional choices for hospitals and critical access hospitals	
Record advance directives for patients 65 years of age or older	More than 50% of patients 65 years of age or older have an indication of an advance directive status recorded
Submit of electronic data on reportable laboratory results to public health agencies	Perform at least one test of data submission and follow-up submission (where public health agencies can accept electronic data)
Additional choices for eligible professionals	
Send reminders to patients (per patient preference) for preventive and follow-up care	More than 20% or patients 65 years of age or older or 5 years of age or younger are sent appropriate reminders
Provide patients with timely electronic access to their health information (including laboratory results, problem list, medication lists, medication allergies)	More than 10% of patients are provided electronic access to information within 4 days of its being updated in the EHR

Source: David Blumenthal, M.D., M.P.P., and Marilyn Tavenner, R.N., M.H.A. The "Meaningful Use" Regulation for Electronic Health Records, NEJM | July 13, 2010

To suggest article topics for consideration in the next OPM Newsletter, please email us at Novartis_OPM@xcenda.com

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