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Two Companion Rules Completing the Stage 1 Criteria for the Electronic Health Record Incentive Program Released

Background

On July 13, 2010, the Department of Health and Human Services (HHS) released two key companion rules that form the basis of the final requirements for Stage 1[1] of the EHR incentive program. In particular, the Centers for Medicare and Medicaid Services (CMS) released the long-awaited Meaningful Use Final Rule (the MU Final Rule) defining the Stage 1 criteria that eligible professionals (EPs)[2], eligible hospitals (EHs)[3] and critical access hospitals (CAHs) must meet to qualify for Medicare and Medicaid incentives under the Health Information Technology for Economic and Clinical Health Act (the HITECH Act)[4]. On the same day, The Office of the National Coordinator for Health Information Technology (ONC) issued a companion Standards Final Rule identifying the standards and certification criteria for the certification of EHR technology, which will enable EHR vendors to develop EHR systems with the required technical functionality to qualify for incentives. Both rules had been issued as Proposed Rules earlier this year on January 13, 2010. This Client Bulletin discusses the Stage 1 meaningful use criteria in the MU Final Rule.[4]

Following the release of the MU Proposed Rule, CMS received over 2,000 comments through March 15, 2010. The MU Final Rule reflects CMS' balance of stakeholder concerns against the federal policy mandate to move the nation toward meaningful use of EHR technology. As discussed further below, the basic Stage 1 EHR incentive program requirements finalized in the MU Final Rule remain generally similar to the MU Proposed Rule. However, the MU Final Rule relaxes some of the measures that must be reported, expands eligibility, and harmonizes the criteria across CMS programs, such as existing pilot programs and quality programs, somewhat.

The HITECH Act established three different EHR incentive programs for each of the Medicare fee for service (FFS) program, Medicare Advantage plan (MA) program, and the Medicaid program. To qualify for incentives under *any* of the three programs requires 1) use of a certified EHR in a *meaningful manner*; 2) use of certified EHR technology for *electronic exchange* of health information to improve quality of health care; and 3) use of certified EHR technology to submit to CMS clinical quality measures, and other similar measures determined by CMS.

Comparing the MU Proposed Rule to MU Final Rule

Changes From The MU Proposed Rule. Among the most significant changes from the MU Proposed Rule to the MU Final Rule is an expansion of EP eligibility. Specifically, the MU Final Rule narrowed the definition of hospital-based EPs, which are not eligible for Medicare FFS or Medicaid program incentives, by adopting the definition from the recently passed Continuing Extension Act of 2010, which defined hospital-based EPs as those EPs performing substantially all (90 percent or more) of their services in either an inpatient hospital setting or hospital emergency department. This means that ambulatory EPs that do *not* perform 90 percent or more of their services in the inpatient or emergency department of a hospital will now qualify for Medicare FFS and Medicaid incentives. This makes EPs practicing in provider-based physician clinics operated by EHs and other EPs

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practicing in hospital ambulatory settings eligible for the Medicare FFS and Medicaid incentive program. The MU Final Rule also added CAHs to the definition of acute care hospitals for purposes of the Medicaid incentive program.

In a nod to stakeholder concerns, the MU Final Rule decreased the number of objectives that EPs (must report on 20 of 25), EHs (must report on 19 of 24), and CAHs must meet to qualify for Stage 1 incentives, and also decreased the threshold measure that must be demonstrated to meet Stage 1 for certain objectives to the middle to lower range of what was proposed. The MU Final Rule divides the objectives (25 for EPs and 24 for EHs) into a "core set," all of which must be met, and a second "menu set" of ten objectives of which providers must meet five objectives (one of which must be a Population and Public Health objective) and may defer five objectives in Stage 1 (2011 and 2012). This approach assures that all providers meet the most essential objectives of meaningful use to qualify for Stage 1 incentives, but also builds in flexibility to allow providers to create an individualized path towards meaningful use for less essential objectives. Another key change is that objectives for administrative transactions (claims and eligibility) were removed. See attached Charts 1 and 2 Meaningful Use "Core Set" and "Menu Set" Objectives and Measures.

Another important change in the MU Final Rule is the reduction in requirements to report certain clinical quality measures from the EHR. In particular, EPs must report on six total clinical quality measures, three required core clinical quality measures (e.g. hypertension: blood pressure measurement) and three additional clinical quality measures (from a set of 38, not including the core measures). In 2011 EPs, EHs and CAHs can submit CQM data by attestation; however in 2012 they must submit CQM data electronically. In addition, CMS finalized only those clinical quality measures that can be automatically calculated by a certified EHR and limited the measures to those for which electronic specifications are currently available.

Other significant changes from the MU Proposed Rule to the MU Final Rule include adding an alternative to calculate Medicaid patient volume for patients in managed care plans and clarifying that State Medicaid programs can start making incentive payments no sooner than 2011.

MU Proposed Rule Concepts Finalized. The MU Final Rule closed the debate on certain aspects of the MU Proposed Rule, including by finalizing that payments to EHs will be made based on their CMS Certification Numbers. CMS reasoned that this approach is most consistent with Medicare policy regarding the meaning of a "subsection (d) hospital" (an EH) under other hospital payment regulations. Stakeholders had expressed concern that using the CMS Certification Number disadvantages health systems that have enrolled multiple hospitals with Medicare under one CMS Certification Number, versus those health systems that have enrolled each hospital under an individual CMS Certification Number. Payments to EPs will be made based on their National Provider Identifiers (NPIs).

The MU Final Rule also finalized an objective for condition-specific patient education resources for EPs and EHs, as well as for EHs to record advanced directives.

A detailed overview of the MU Final Rule's requirements is set forth below.

Footnotes

[1]CMS plans to propose Stage 2 "meaningful use" requirements in future rulemaking, which are expected to expand upon the Stage 1 requirements in the MU Final Rule with a greater emphasis on health information exchange across institutional boundaries.

[2]A Medicare FFS incentive program EP is a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, who is legally authorized to practice under state law. The Medicaid incentive program uses a slightly different definition of EP, which includes physicians, dentists, certified nurse-midwives, nurse practitioners, and physician assistants practicing in federally qualified health centers led by a physician assistant or rural health clinics led by a physician assistant.

[3]For the Medicare FFS incentive program, and EH is a "subsection (d) hospital" that is paid under the hospital inpatient prospective payment system and is located in the 50 states or Washington, DC, which includes most acute care hospitals. Medicaid incentive program EHs are acute care hospitals (including critical access hospitals) and children's hospitals.

[4]42 U.S.C. 1395w-4.

[5]On June 24, 2010, ONC published yet a third rule, the Temporary Certification Program Final Rule establishing a *temporary* certification program by which ONC authorizes organizations to test and certify complete EHRs and EHR modules. ONC plans to issue a separate final rule to establish a *permanent* certification program to replace the temporary certification.

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The MU Final Rule Requirements

Meaningful Users of EHR

Under the MU Final Rule, EPs, EHs, and CAHs can qualify for Medicare and Medicaid incentive payments if they adopt certified EHR technology and meaningfully use it to achieve specified objectives and demonstrate measures. A "meaningful EHR user" is defined as an EP, EH, or CAH that, for an EHR reporting period for a payment year, demonstrates meaningful use of certified EHR technology by meeting the applicable objectives and associated measures outlined below. For EPs, the EHR reporting period for the first payment year is any continuous 90-day period within a calendar year and for the second, third, fourth, fifth and sixth payment years the reporting period is the calendar year. For EHs and CAHs, the EHR reporting period for the first payment year is any continuous 90-day period within a federal fiscal year, and for the second, third, fourth, fifth and sixth payment years the reporting period is one year. The first payment year is the first calendar year for which an EP receives an incentive payment, or the first federal fiscal year for which an EH or CAH receives an incentive payment. The second, third, fourth, fifth and sixth payment years must be successive and immediately follow the first payment year.

Meaningful Use Criteria

To meet the definition of a "meaningful user," EPs, EHs and CAHs must meet all "core set" objectives and demonstrate the associated measures of the Stage 1 criteria specified in the attached Chart 1, unless they meet the exclusion criteria for non-applicable objectives.[1] Additionally, the EP, EH and CAH must meet five of the objectives from the attached Chart 2 "menu set." At least one of the five objectives selected must be a Population and Public Health category. The remaining five "core set" objectives may be deferred in Stage 1 (2011-2012).

Demonstration of Meaningful Use

To demonstrate "meaningful use," EPs, EHs and CAHs must attest, through a secure mechanism in a manner specified by CMS, that during the EHR reporting period they: (1) used the certified EHR technology and specify the technology used; (2) satisfied the required objectives and associated measures; and (3) specify the EHR reporting period and provide the result of each applicable measure for all patients seen during the EHR reporting period for which the selected measure is applicable.[2]

An EP, EH or CAH must submit the following information to CMS in the first payment year, in a manner specified by CMS:

- Name of the EP, EH or CAH
- National Provider Identifier
- Business address and phone number
- Such other information as specified by CMS (which CMS may specify later)
- CMS certification number
- Taxpayer Identification Number

Registration for both the Medicare and Medicaid incentive programs will occur at one virtual location managed by CMS. EPs and EHs can register starting in January 2011 and attestations may be made starting in April 2011. CMS projects Medicare EHR incentive payments will begin in mid-May 2011. State timelines are less clear as they are subject to CMS approval of the State Medicaid HIT plan outlining how each state will implement and oversee its Medicaid incentive program.

Medicare Incentive Payments

Eligible Professional. Under the Medicare FFS incentive program, a qualifying EP[3] may receive Medicare EHR incentive payments for up to five payment years, with payments beginning as early as January, 2011. In general, the maximum amount of total incentive payments that an EP can receive under the Medicare program is $44,000. In general, a qualifying EP can receive an annual incentive payment as high as $18,000 if their first payment year is 2011 or 2012. The annual incentive payment limits for 2011 or 2012 are $18,000, $12,000, $8,000, $4,000 and $2,000. If a qualifying

[1]An EP, EH or CAH may exclude a particular criteria when they can attest that the particular criteria is not applicable by meeting the exclusion requirement listed on Chart 1.

[2]Additionally, Medicaid EPs, EHs and CAHs must also demonstrate meeting the state revised definition of "meaningful use" using the method approved by CMS. However, Medicaid eligible EPs, hospitals and CAHs that adopt, implement or upgrade certified EHR technology in their first payment year, need not demonstrate meaningful use until the second payment year.

[3]A Medicare FFS program qualifying EP is one who demonstrates meaningful use for the EHR reporting period.

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EP's first payment year starts in 2013, the EP can only receive a maximum of $39,000 with four annual incentive payments of $15,000, $12,000, $8,000, and $4000. In year 2014, the maximum drops to $24,000 with 3 annual payments of $12,000, $8,000 and $4,000. However, an EP who predominantly furnishes services in a geographic Health Professional Shortage Area (HPSA)[4] is eligible for a 10 percent increase in the maximum incentive payment amount.

EPs who cannot demonstrate meaningful EHR use by 2015 will be subject to penalties in the form of lower Medicare reimbursement for professional services beginning in 2015. Payment reductions of the Medicare physician fee schedule reimbursed amount for professional services are 99% for 2015, 98% for 2016, and 97% for 2017. However, the Secretary of HHS can exempt an EP from the payments reductions if the Secretary determines that compliance with the requirement for being a meaningful user would result in a significant hardship for the EP.

Significantly, EPs who meet the eligibility requirements for both the Medicare FFS and the Medicaid incentive programs may participate in only one program and must designate the program in which they would like to participate. But EPs are allowed to change their program selection once during payment years 2012 through 2014.

Eligible Hospitals. EHs may receive Medicare incentive payments for up to four payment years for the fiscal year beginning in their Medicare fiscal year (FY) 2010, or October 2010, provided they are able to demonstrate meaningful use. EHs may not receive incentive payments after 2016. Further, some EHs may qualify to receive payments from *both* the Medicare and Medicaid EHR incentive programs. The initial Medicare incentive payment amount for EHs is equal to one of the following:

- For hospitals with 1,149 acute care inpatient discharges or less = $2,000,000
- For hospitals with at least 1,150 but no more than 23,000 acute care inpatient discharges = $2,000,000 + [$200x(number of discharges for the hospital -1,149)]
- For hospitals with more than 23,000 acute care inpatient discharges = $6,370,200

Incentive payments for EHs are phased down over the 4-year period using a transition factor which will reduce the initial payment amount by 25% each year after the first year.

Eligible Critical Access Hospitals. Qualifying CAHs may receive Medicare incentive payments for up to four payment years beginning with cost reporting periods that begin in FY 2011 and ending with a cost reporting period that begins in FY 2015. CAHs can receive Medicare incentive payments for the reasonable costs incurred for the purchase of depreciable assets like computers and associated hardware and software, necessary to administer certified EHR technology, excluding any depreciation and interest expenses associated with the acquisition. A qualifying CAH will receive an incentive payment amount equal to the product of its reasonable costs incurred for the purchase of certified EHR technology and its Medicare share percentage. The Medicare share percentage equals the lesser of (1) 100 percent; or (2) the sum of the Medicare share fraction for the CAH and 20 percentage points. CAHs that cannot demonstrate meaningful EHR use by FY 2015 are also subject to penalties in the form of downward payment adjustments. Beginning in or after FY 2015, if a CAH is not a qualifying CAH, then the reasonable costs of the CAH in providing CAH services to its inpatients are adjusted by the following applicable percentages: 100.66% for FY 2015; 100.33% for FY 2016; and, 100% for FY 2017 and each subsequent fiscal year.

Medicaid Incentive Payments

The final rule gives States the option to provide for payments to Medicaid providers for adopting, implementing, or upgrading certified EHR technology or for meaningful use of such technology. Additionally, the final rule provides enhanced federal financial participation (FFP) to States to administer these incentive payments.

Eligible Professional. As stated above, Medicaid uses a slightly different definition for EPs. Further, Medicaid EPs may not be hospital-based and must meet one of the following criteria:

- Have a minimum 30 percent patient volume attributable to individuals receiving Medicaid.
- Have a minimum 20 percent patient volume attributable to individuals receiving Medicaid, and be a pediatrician.
- Practice predominately in a Federally Qualified Health Center or Rural Health Clinic and have a minimum 30 percent patient volume attributable to needy individuals.

[4] An HPSA means any of the following which the Secretary determines has a shortage of health professional(s): (1) An urban or rural area (which need not conform to the geographic boundaries of a political subdivision and which is a rational area for the delivery of health services); (2) a population group; or (3) a public or nonprofit private medical facility.

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Medicaid EPs who are also eligible as a Medicare EP must choose between the Medicare and Medicaid incentive programs when they register. An EP may change his or her EHR incentive election payment program once. An EP who switches programs is not permitted to collect more than the maximum Medicaid incentive ($63,750) across all payment years.

A Medicaid EP must adopt, implement, upgrade or demonstrate meaningful use of certified EHR technology in the first year of participation to qualify for Medicaid incentive payments. Medicaid EPs must then demonstrate meaningful use in years 2-6 of participation. For calendar years 2011-2021, the maximum amount of total incentive payments that a Medicaid EP can receive is $63,750 over 6 years. The annual incentive payment limits in the first, second, third, fourth, fifth, and sixth years are $21,250, $$8,500, $8,500, $8,500, $8,500 and $8,500 respectively.

It is important to note that all Medicare providers will have a payment reduction in 2015 if they are not demonstrating meaningful use in either the Medicare or Medicaid EHR incentive program.

Eligible Hospital. Acute care hospitals with at least a 10 percent Medicaid patient volume for each year for which the hospital seeks an EHR incentive payment and children's hospitals are eligible to receive Medicaid EHR incentive payments. Unlike EPs, hospitals that meet both sets of eligibility criteria may receive incentive payments from both Medicare and Medicaid. The incentive payments provided to critical access hospitals and children's hospitals under the Medicaid incentive program are analogous to those provided to Medicare EPs.

Medicaid EHs and CAHs must adopt, implement, upgrade or demonstrate meaningful use of certified EHR technology in the first year of participation to qualify for Medicaid incentive payments. Note that there is no EHR reporting period for adopting, implementing or upgrading EHR technology for Medicaid EH's and CAH's first payment year. Medicaid EHs and CAHs must demonstrate meaningful use over a 90-day reporting period during their second year of participation and over 12 months for their third and subsequent years. Hospitals that are eligible for both Medicare and Medicaid incentive payments would be well served to plan their ability to demonstrate and report meaningful use and then strategically register to receive the first Medicaid incentive payment in the year before they are able to demonstrate and report meaningful use. This would allow a hospital to adopt, implement or upgrade EHR and collect the Medicaid Year 1 payment, and then in the next year, the hospital should demonstrate meaningful use for a 90 day period and collect the Medicaid Year 2 payment and the Medicare Year 1 payment.

CHART 1

STAGE 1 MEANINGFUL USE "CORE SET" OBJECTIVES AND MEASURES - ALL REQUIRED

EP Objective	EH/CAH Objective	Measure[1]	Applicable Exclusion
Use computerized provider order entry (CPOE) for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines.	Same as EP.	More than 30% of all unique patients[2] with at least one medication in their medication list have at least one medication order entered using CPOE.	Any EP who writes fewer that 100 prescriptions during the EHR reporting period.
Implement drug-drug and drug-allergy interaction checks.	Same as EP.	This functionality is enabled for the entire EHR reporting period.	N/A
Maintain an up-to-date problem list of current and active diagnoses.	Same as EP.	More than 80% of all unique patients have at least one entry or an indication that no problems are known for the patient recorded as structured data.	N/A
Generate and transmit permissible prescriptions electronically.	N/A	More than 40% of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology.	Any EP who writes fewer that 100 prescriptions during the EHR reporting period.
Maintain active medication list.	Same as EP.	More than 80% of all unique patients have at least one entry or an indication that the patient is not currently prescribed any medication recorded as structured data.	N/A

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EP Objective	EH/CAH Objective	Measure[1]	Applicable Exclusion
Maintain active medication allergy list.	Same as EP.	More than 80% of all unique patients have at least one entry or an indication that the patient has no known medication allergies recorded as structured data.	N/A
Record all of the following demographics: preferred language; gender; race; ethnicity; and, date of birth.	Same as EP plus the following: date and preliminary cause of death in the event of mortality in the EH or CAH.	More than 50% of all unique patients have demographics recorded as structured data.	N/A.
Record and chart changes in the following vital statistics: height; weight; blood pressure; calculate and display body mass index (BMI); and, plot and display growth charts for children 2-20 years, including BMI.	Same as EP.	More than 50% of all unique patients age 2 and over, height, weight and blood pressure are recorded as structured data.	Any EP who either sees no patients 2 years or older, or who believes that all three vital signs (height, weight and blood pressure) of their patients have no relevance to their scope of practice.
Record smoking status for patients 13 years old or older.	Same as EP.	More than 50& of all unique patients 13 years old or older have smoking status recorded as structured data.	Any EP who sees no patients 13 years or older or any EH or CAH that admits no patients 13 years or older.
Report ambulatory clinical quality measures to CMS, or in the case of Medicaid EPs, to the state.	Report hospital clinical quality measures to CMS, or in the case of Medicaid EPs, to the state.	Successfully report the required quality measures to CMS or the state.	N/A
Implement one clinical decision support rule relevant to specialty or high clinical priority along with the ability to track compliance with that rule.	Implement one clinical decision support rule related to a high priority hospital condition along with the ability to track compliance with that rule.	Implement one clinical decision support rule.	N/A
Provide patients with an electronic copy of their health information upon request.	Same as EP.	More than 50% of all patients who request an electronic copy of their health information are provided it within 3 business days.	Any EP, EH or CAH that has no requests from patients or their agents for an electronic copy of patient health information during the EHR reporting period.
Provide clinical summaries for patients for each office visit.	Provide patients with an electronic copy of their discharge instructions at the time of discharge, upon request.	For EPs, clinical summaries provided to patients for more than 50% of all office visits within 3 business days. For EHs and CAHs, more than 50% of patients who are discharged and request an electronic copy of their discharge instructions are provided with them.	Any EP that has no office visits during the EHR reporting period. Any EH or CAH that has no requests from patients or their agents for an electronic copy of their discharge instructions during the EHR reporting period.
Capability to exchange key clinical information among providers of care and patient authorized entities electronically.	Same as EP.	Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information.	N/A
Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.	Same as EP.	Conduct or review a security risk analysis and implement security updates as necessary and correct identified security deficiencies as part of the risk management process.	N/A

CHART 2
STAGE 1 MEANINGFUL USE "MENU SET" OBJECTIVES AND MEASURES – CAN DEFER UP TO FIVE (BUT PICK ONE POPULATION OBJECTIVE)

EP Objective	EH/CAH Objective	Measure[2]	Applicable Exclusion
Implement drug-formulary checks.	Same as EP.	Enabled this functionality and have access to at least one internal or external formulary for the entire EHR reporting period.	
N/A	Record advance directives for patients 65 years old or older.	More than 50% of all unique patients 65 years old or older have an indication of an advanced directives status recorded as structured data.	An EH or CAH that admits no patients age 65 years old or older during the EHR reporting period.
Incorporate clinical lab-test results into EHR structured data.	Same as EP.	More than 40% of all clinical lab test results during the EHR reporting period whose results are either in a positive or negative or numerical format are incorporated in certified EHR technology as structured data.	An EP who orders no lab tests whose results are either in a positive or negative or numerical format during the EHR reporting period.
Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research or outreach.	Same as EP.	Generate at least one report listing patients with a specific condition.	N/A
Send reminders to patients per patient preference for preventative/follow-up care.	N/A	More than 20% of all patients 65 years or older or 5 years old or younger were sent appropriate reminders during the EHR reporting period.	An EP who has no patients 65 years old or older or 5 years old or younger with records maintained using certified EHR technology.
Provide patients with timely electronic access to their health information within 4 business days of the information being available to the EP.	N/A	At least 10% of all unique patients seen by the EP are provided timely electronic access to their health information, subject to the EP's discretion to withhold certain information.	Any EP that neither orders nor creates any of the specified information during the EHR reporting period.
Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient if appropriate.	Same as EP.	More than 10% of all unique patients are provided patient-specific education resources.	N/A
Performance of medication reconciliation when the patient is transitioned into the care of the EP, EH or CAH or when the EP, EH or CAH believes an encounter is relevant.	Same as EP.	Medication reconciliation for more than 50% of transitions of care.	Any EP, EH or CAH that is not the recipient of any transitions of care during the EHR reporting period.
The EP, EH or CAH that transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.	Same as EP.	Provide a summary of care record for more than 50% of transitions of care and referrals.	Any EP, EH or CAH that neither transfers a patient to another setting nor refers a patient to another provider during the EHR reporting period.

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EP Objective	EH/CAH Objective	Measure[2]	Applicable Exclusion
Capability to submit electronic data to immunization registries or immunization information systems and actual submission according to applicable law and practice.	Same as EP.	Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries and follow-up submission if the test is successful.	Any EP, EH or CAR that administers no immunizations during the EHR reporting period or where no immunization registry has the capacity to receive the information electronically.
N/A	Capability to submit electronic data on reportable lab results to public health agencies and actual submission according to applicable law and practice.	Performed at least one test of certified EHR technology's capacity to provide electronic submission of reportable lab results to public health agencies and follow-up submission if the test is successful.	No public health agency to which the EH or CAH submits such information has the capacity to receive the information electronically.
Capability to submit electronic syndromic surveillance data to public health agencies and actual submission according to applicable law and practice.	Same as EP.	Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies and follow-up submission if the test is successful.	

Footnotes

[1]For EPs, measures referencing a percentage of patients are based on the number of patients seen by the EP. For EHs and CAHs, measures referencing a percentage of patients are based on the number of patients admitted to the hospital.

[2]For EPs, measures referencing a percentage of patients are based on the number of patients seen by the EP. For EHs and CAHs, measures referencing a percentage of patients are based on the number of patients admitted to the hospital.

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