



# American Hospital Association

**Sonnenschein**  
Sonnenschein Nath & Rosenthal LLP

## Medicare Advantage

### A Primer for America's Hospitals

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#### Session 3: Regulatory Issues Affecting Providers

#### **I. Introduction**

In this Primer, we discuss Medicare Advantage (“MA”) program regulations that directly or indirectly impact providers.<sup>1</sup> These include, for instance, MA rules that dictate the qualifications that institutional providers must have in order to serve as MA network providers and that govern the relationship between MA organizations and providers in certain fundamental respects, including provider selection and credentialing. We also describe the basic provider protections set forth in regulation, which are particularly important for non-contracted providers.<sup>2</sup>

As noted in earlier sessions, the MA program allows MA organizations and their network providers significant flexibility in establishing the terms and conditions of payment and participation. That said, such negotiations are subject to, and informed by, numerous regulatory and program restrictions. Thus, for instance, the Centers for Medicare & Medicaid Services (“CMS”) mandates that specific contract terms be included in all written agreements between

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<sup>1</sup> This discussion is not meant to be comprehensive. The complete set of MA rules that apply to providers and others are contained in 42 C.F.R. Part 422, available at <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=42583b0a0594c4a1d5afa09f244ec267&rgn=div5&view=text&node=42:2.0.1.2.22&idno=42>.

Regulations governing payment arrangements between MA organizations and providers were addressed in the Session II Primer, and will not be repeated here.

<sup>2</sup> Since the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the “MMA”) significantly expanded the scope of Federal preemption of State law in the MA context, the rights of non-contracted providers are now largely governed by the MA program rules. For instance, the MA regulations establish prompt payment standards that apply to non-contracted providers furnishing health care services to MA plan enrollees. 42 C.F.R. § 422.520(a).

For additional information concerning federal preemption under the MA program, see Session I Primer: The Basics, at 15. See also 42 C.F.R. § 422.402 and 70 Fed. Reg. 4588, 4663 (Jan. 28, 2005).

MA organizations and their providers, and prohibits other terms from appearing in such contracts. Moreover, as part of the contracting process, providers must agree to comply with the MA organization's policies and procedures. This has significant practical consequences for providers since CMS requires MA organizations to have "policies and procedures" for complying with numerous specific regulatory requirements. As a result, providers are bound through their contracts with MA organizations to comply with a host of regulatory requirements (many of which would not otherwise directly apply to them). Providers should, therefore, carefully review the MA organization's policies and procedures (typically contained in the MA plan manual) to assess the full extent of the contractual commitments they are being asked to undertake.<sup>3</sup>

## **II. Regulations Governing the Relationship Between MA Organizations and Providers**

### **A. Physician Involvement in Policy-Making**

#### **1. Consultation on Medical and Related Policies**

MA organizations must establish formal procedures for consulting with network physicians regarding the organization's medical policy, quality improvement programs and medical management procedures.<sup>4</sup> The MA organization's practice and utilization management guidelines must be developed in consultation with network physicians and (1) be based on reasonable medical evidence or a consensus of health care professionals in the particular field; (2) consider the needs of the enrolled population; and (3) be reviewed and updated periodically.<sup>5</sup> The MA organization must communicate these guidelines to providers and, as appropriate, to enrollees, and ensure that decisions with respect to utilization management, enrollee education, and coverage of services, are consistent with the guidelines.<sup>6</sup>

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<sup>3</sup> Providers should also seek to obtain commitments from MA organizations that (1) such organizations will promptly notify them of changes in the MA plan's policies and procedures, and (2) that such changes will not be effective until a set period (e.g., thirty days) after notice has been provided (unless implementation is expressly required earlier by regulation or CMS guidance).

<sup>4</sup> 42 C.F.R. § 422.202(b); Medicare Managed Care Manual ("MCM"), Ch. 6, § 20.1.

<sup>5</sup> Id. § 422.202(b)(1).

<sup>6</sup> Id. § 422.202(b)(2) and (3).

## 2. Consultation on Credentialing Policies

MA organizations must develop written policies and procedures governing selection and evaluation of providers for participation in the MA organization's network. Policies and procedures governing participation by physicians and other health care professionals must conform with the credentialing and re-credentialing requirements, and the anti-discrimination rules, set forth below.<sup>7</sup> The credentialing and re-credentialing standards for types of providers and for specialists should be reviewed by clinical peers, through establishment of a credentialing committee or other mechanism.<sup>8</sup> In addition, the MA organization must establish a process for peer review when the MA organization is considering employing or contracting with a provider who does not meet the credentialing standards.<sup>9</sup>

### **B. Written Procedures for Physician Participation in MA Networks (and for Termination or Suspension of Physician Participation)**

MA organizations operating coordinated care plans and network Medical Savings Account ("MSA") plans must establish "reasonable procedures" for the participation of individual physicians and for the management and participation of groups of physicians.<sup>10</sup> Such procedures must include furnishing written notice of (1) the rules of participation (including terms of payment, credentialing, and other rules directly related to participation decisions); (2) material changes in participation rules before the changes are put into effect; and (3) participation decisions that are adverse to physicians.<sup>11</sup> In addition, such MA plans must offer a process for appealing adverse participation decisions, which includes the physician's right to present information and his or her views on the decision.<sup>12</sup>

Special rules apply to termination or suspension of physician contracts by MA Plans.<sup>13</sup> Specifically, an MA organization that suspends or terminates an MA physician agreement must give the affected physician written notice of (1) the reason for the action, including (if relevant) the standards and profiling data used to evaluate the physician and the numbers and mix of physicians needed by the MA organization, and (2) the affected physician's right to appeal the action (and the process and timing for requesting a hearing).<sup>14</sup> The MA organization must ensure that the majority of the hearing panel members are peers of the affected physician.<sup>15</sup>

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<sup>7</sup> Id. § 422.204(a).

<sup>8</sup> Id. § 422.204(b)(2)(iii); MCM, Ch. 6, § 20.2.

<sup>9</sup> MCM, Ch. 6, § 20.2.

<sup>10</sup> 42 C.F.R. § 422.202(a).

<sup>11</sup> Id.

<sup>12</sup> Id. § 422.202(a)(4).

<sup>13</sup> Id. § 422.202(d).

<sup>14</sup> Id. § 422.202(d)(1).

<sup>15</sup> Id. § 422.202(d)(2).

The notice and appeal requirements outlined above apply regardless of whether suspension or termination of the physician contract is due to quality deficiencies, unless the physician voluntarily agrees to leave the organization's network.<sup>16</sup> These requirements also apply to non-renewal of contracts.<sup>17</sup>

The MA organization and the contracting physician must each provide at least 60 days advance written notice to the other party before terminating a participation agreement without cause.<sup>18</sup> If the MA organization suspends or terminates a contract with a physician because of deficiencies in quality of care, the MA organization must provide written notice of that action to licensing or disciplinary bodies or to other appropriate agencies.<sup>19</sup>

MA organizations must apply the same participation procedures and guidelines to individual physicians as to physicians within subcontracted physician groups.<sup>20</sup>

### **C. Non-Interference with Professional Advice**

An MA organization may not prohibit or otherwise restrict a health care professional, acting within the lawful scope of his or her practice, from "advising, or advocating on behalf of" an MA plan enrollee about (1) the patient's health status, medical care, or treatment options; (2) the risks, benefits, and consequences of treatment or non-treatment; or (3) the opportunity for the individual to refuse treatment and/or to express preferences about future treatment decisions.<sup>21</sup> That said, an MA plan is not required to cover, furnish or pay for a particular counseling or referral service if the MA organization objects on moral or religious grounds and certain other criteria are met.<sup>22</sup>

Health care professionals are required to provide information regarding treatment options, including the option of no treatment.<sup>23</sup> Additionally, health care professionals are required to ensure that individuals with disabilities have effective communications with participants throughout the health system in making decisions regarding treatment options.<sup>24</sup>

### **D. Anti-Discrimination Rules**

In general, MA organizations are free to select their network providers, subject to the policies and procedures developed by the MA organization concerning provider selection,

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<sup>16</sup> MCM, Ch. 6, § 60.4.

<sup>17</sup> Id.

<sup>18</sup> Id.

<sup>19</sup> 42 C.F.R. § 422.202(d)(3).

<sup>20</sup> Id. § 422.202(c).

<sup>21</sup> Id. § 422.206(a).

<sup>22</sup> Id. § 422.206(b).

<sup>23</sup> Id. § 422.206(a).

<sup>24</sup> Id.

credentialing and qualification, and CMS access requirements.<sup>25</sup> That said, MA organizations may not discriminate, in terms of participation, reimbursement, or indemnification, against any health care professional acting within the scope of his or her licensure or certification under state law, solely on the basis of the license or certification.<sup>26</sup> For instance, an MA organization could not have a policy excluding Licensed Clinical Social Workers (“LCSWs”) from providing mental health services if the state’s LCSW licensing law and regulations authorize LCSWs to provide mental health services. In cases where an MA organization declines to include a given provider or group of providers in its network, the MA organization must provide a written notice stating the reason for its decision.<sup>27</sup>

The prohibition on discrimination outlined above does not, however, prevent an MA organization from (1) refusing to grant participation to health care professionals in excess of the number necessary to meet the needs of the MA plan enrollees (except that MA PFFS plans may not refuse to contract with providers on this basis); (2) using different reimbursement amounts for different specialties or for different practitioners in the same specialty; or (3) implementing measures designed to maintain quality and cost controls consistent with the MA organization’s responsibilities.<sup>28</sup>

### **III. Rules Governing Eligibility to Become a Network Provider/Receive MA Payments**

#### **A. Excluded Providers**

MA organizations are expressly prohibited from employing or contracting with individuals or entities that are excluded from participating in Medicare (or with any entities that employ or contract with individuals excluded from participating in Medicare) for the provision of health care, utilization review and other designated services.<sup>29</sup> MA organizations employing or contracting with health care providers must check the list of excluded parties issued by the Department of Health and Human Services Office of Inspector General (“OIG”) (available at [http://www.oig.hhs.gov/fraud/exclusions/list\\_of\\_excluded.html](http://www.oig.hhs.gov/fraud/exclusions/list_of_excluded.html)) upon each new issuance of the list in order to avoid hiring, contracting with, or continuing to employ or contract with individuals named on the list.<sup>30</sup>

Given this requirement, and the fact that “intermediate sanctions” may be imposed against an MA organization violating this prohibition, MA organizations will generally request that providers agree to (1) represent and warrant that they are not excluded from the Medicare

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<sup>25</sup> Id. § 422.205.

<sup>26</sup> Id. § 422.205(a).

<sup>27</sup> Id.

<sup>28</sup> Id. § 422.205(b).

<sup>29</sup> Id. §§ 422.204(b)(4) and 422.752(a)(8). MA organizations may not make payments to excluded providers, except for emergency services furnished to MA enrollees in limited circumstances. See MCM, Ch. 6, § 60.2; 42 C.F.R. § 1001.1901.

<sup>30</sup> MCM, Ch. 6, § 60.2.

program (or employ individuals or entities excluded from the Medicare program), and (2) provide prompt notice of any relevant exclusion from Medicare. MA organizations typically seek authority to terminate the provider agreement “for cause” if the provider is excluded from participation in the Medicare program at any time during the course of the agreement.

## **B. “Opt out” Providers**

The Medicare regulations permit physicians and practitioners to "opt-out" of participation in the Medicare program for a two-year period by filing a required affidavit.<sup>31</sup> Physicians and practitioners who have opted out of Medicare may enter into private contracts with Medicare beneficiaries for the furnishing of items or services that would otherwise be covered by Medicare.<sup>32</sup> Under such private contracts, Medicare beneficiaries agree to give up Medicare payment for services furnished by the physician or practitioner and to pay for such services themselves, without regard to any limits that would otherwise apply to what the physician or practitioner could charge.<sup>33</sup>

The MA regulations contain special rules regarding treatment of “opt out” providers. Thus, an MA organization may not pay, directly or indirectly, for services (other than emergency or urgently needed services) furnished to an MA plan enrollee by a physician or other practitioner who has opted out of Medicare by filing the appropriate affidavit. Such physicians and practitioners may not seek or accept reimbursement from Medicare for a period of two years, except for the provision of emergency and urgently needed services.<sup>34</sup> MA organizations are required to check the list of opt-out providers maintained by their local Medicare Part B carrier on a “regular” basis in order to avoid paying such opt-out providers (except in emergency situations).<sup>35</sup>

## **C. Credentialing, Monitoring and Re-credentialing**

### **1. Physicians and other Health Care Professionals**

The MA regulations require that MA organizations review the qualifications (and other relevant information) pertaining to health care professionals who seek to be directly employed by the MA organization (for instance, as employees of a staff model health maintenance organization) or who seek a participation agreement with the MA organization. The required procedures are summarized below.

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<sup>31</sup> 42 C.F.R. § 405.405(b). This period may be terminated early or renewed for another two year period. *Id.* §§ 405.405 and 405.445.

<sup>32</sup> *Id.* § 405.405(a).

<sup>33</sup> Centers for Medicare & Medicaid Services, Frequently Asked Questions (“CMS FAQ”), ID #357, available generally at [http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std\\_alp.php](http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_alp.php). The requirements for private contracts are set forth at 42 C.F.R. § 405.415.

<sup>34</sup> MCM, Ch. 6, § 60.2. *See also* 42 C.F.R. § 405.440.

<sup>35</sup> *Id.* *See also* MCM, Ch. 6, § 60.2.

a) Who must be credentialed?

The MA organization must credential (1) all physicians who provide services to the MA organization's enrollees, including members of physician groups, and (2) all other types of health care professionals who provide services to the MA organization's enrollees and who are permitted to practice independently under state law.<sup>36</sup>

The MA organization is not required to credential: (1) health care professionals who are permitted to furnish services only under the direct supervision of another practitioner, or (2) hospital-based health care professionals who provide services to enrollees "incident to" hospital services, unless those health care professionals are separately identified in enrollee literature as available to enrollees (i.e., health care professionals who are listed in the network directory).<sup>37</sup>

b) What are the credentialing requirements?

The initial credentialing process includes a written application; verification of licensure or certification information from primary sources; review of disciplinary status; confirmation of eligibility for payment under Medicare; and site visits (as appropriate).<sup>38</sup> We discuss select aspects of the credentialing process below.

(1) Application

The written application must be signed and dated and include an attestation by the applicant of the correctness and completeness of the application and other supporting information.<sup>39</sup> The information collected must be no more than six months old on the date on which the health care professional is determined to be eligible for appointment or contract.<sup>40</sup> All items must be verified prior to contracting with or appointing the health care provider, except for a pending Drug Enforcement Agency ("DEA") number.<sup>41</sup>

The written application also must include a relevant work history (covering at least 5 years) and a statement by the applicant regarding (1) any limitations in ability to perform functions of the position, with or without accommodation; (2) history of loss of license and/or felony convictions; and (3) history of loss or limitation of privileges or disciplinary activity.<sup>42</sup>

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<sup>36</sup> MCM, Ch. 6, § 60.3.

<sup>37</sup> Id.

<sup>38</sup> 42 C.F.R. § 422.204(b)(2).

<sup>39</sup> Id.

<sup>40</sup> MCM, Ch. 6, § 60.3.

<sup>41</sup> Id.

<sup>42</sup> Id.

## (2) Information Verification

As part of the credentialing process, the MA organization is required to verify certain information from a “primary source,” which is defined as “an organization or entity with legal responsibility for originating a document and ensuring the accuracy of the information it conveys.”<sup>43</sup> Primary source verification may be achieved through the use of industry-recognized verification sources.<sup>44</sup> An MA organization must verify the following information from primary sources: (1) a current and valid license to practice; (2) education and training records, including evidence of graduation from the appropriate professional school and completion of a residency or specialty training, if applicable; and (3) board certification in each clinical specialty area for which the health care professional is being credentialed if he/she states that he/she is board certified on the application.<sup>45</sup>

The MA organization may use secondary sources to verify the following information: (1) clinical privileges in good standing at the hospital designed by the health care provider, if applicable; (2) current, adequate malpractice insurance meeting the MA organization’s requirements; (3) a valid DEA or Controlled Dangerous Substances (“CDS”) certificate in effect at the time of the credentialing decision; (4) a history of professional liability claims that resulted in settlements or judgments paid by or on behalf of the health care professional; (5) for physicians, any other information from the National Practitioner Data Bank (“NPDB”); (6) information about sanctions or limitations on licensure; and (7) eligibility for participation in Medicare.<sup>46</sup>

## (3) Site Visits

The MA organization must establish a policy of conducting site visits that includes procedures for detecting deficiencies and contains mechanisms for addressing those deficiencies.<sup>47</sup> The MA organization is encouraged to, at a minimum, conduct an initial credentialing site visit of the offices of primary care physicians, obstetricians-gynecologists, or other “high-volume providers” (to be determined by the MA organization).<sup>48</sup> Site visits should include an evaluation of the site’s accessibility, appearance, and adequacy of equipment, based on standards developed by the MA organization, and should include a determination of whether the site conforms to the MA organization’s standards for medical record keeping practices and confidentiality requirements.<sup>49</sup> Although CMS does not mandate a specific methodology for conducting medical record reviews, each MA organization is directed to verify that its

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<sup>43</sup> Id.

<sup>44</sup> Id.

<sup>45</sup> Id.

<sup>46</sup> Id. As noted previously, entities or individuals who have been excluded from participation in Medicare or who have “opted out” of Medicare do not qualify as MA providers. See also 42 C.F.R. § 422.204(b)(4).

<sup>47</sup> MCM, Ch. 6, § 60.3.

<sup>48</sup> Id.

<sup>49</sup> Id.

practitioners' enrollee health records meet the MA organization's standards.<sup>50</sup> If, in the course of regular monitoring, the MA organization becomes aware of conditions at a site that suggest compromised safety or other concerns regarding the delivery of care, the MA organization should perform a site visit as soon as possible to assess the facility and identify necessary corrective action.<sup>51</sup>

c) Does the MA Organization have Interim Monitoring Obligations?

The MA organization is required to develop and implement policies that monitor sanctions and grievances filed against health care professionals in their network.<sup>52</sup> In this regard, the MA organization must regularly obtain and review the following reports and documentation: (a) the OIG list of sanctioned providers; (b) the Medicare carrier list of physicians in the MA service area who have "opted out" of Medicare; (c) beneficiary grievances; and (d) state sanctions and limitations on licensure.

d) When is Re-credentialing Required?

MA organizations are required to have procedures to re-credential physicians and other health care practitioners at least once every three years.<sup>53</sup> This process should include obtaining updates to information obtained in initial credentialing, evaluating performance indicators, and attesting to the correctness and completeness of the new information furnished by the individual.<sup>54</sup> The MA organization is not required to conduct site visits as part of its re-credentialing policies, but may choose to do so in its own discretion.<sup>55</sup>

e) How are Newly Trained Health Care Professionals Credentialed?

In an effort to promote greater MA plan enrollee access to services, and allow newly trained health care professional to begin providing health care services sooner, CMS has authorized a streamlined credentialing process for newly trained health care professionals. For such individuals who have completed all appropriate training and education within the last 12 months, MA organizations may establish policies that permit initial credentialing for a period of up to 60 days, if the MA organization: (1) verifies that the practitioner has a current, valid license from primary sources; (2) verifies malpractice settlements from the last 5 years; (3) has a policy and procedure to ensure that the practitioner meets all standard credentialing requirements after 60 days; and (4) ensures that the MA organization's Credentialing Committee has reviewed

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<sup>50</sup> Id.

<sup>51</sup> Id.

<sup>52</sup> Id.

<sup>53</sup> Id.

<sup>54</sup> Id.

<sup>55</sup> Id.

the case and makes the final determination about granting such an initial 60-day credentialing period.<sup>56</sup>

## 2. Institutional Provider and Supplier Certification

In order for an MA organization to contract with an institutional provider or supplier to be part of its network, the MA organization must first determine that the following three conditions are met: (1) the provider has a signed participation agreements with CMS (or, if relevant, the supplier was approved by CMS as meeting the relevant conditions of coverage for the services); (2) the provider or supplier is licensed to operate in the state and is in compliance with other applicable state or federal requirements, and (3) the provider or supplier has been reviewed and approved by an appropriate accrediting body (e.g., Joint Commission on Accreditation of Healthcare Organizations (“JCAHO”) for hospitals) or meets the standards established by the MA organization itself.<sup>57</sup> Documentation confirming the provider or supplier’s satisfaction of these requirements must be obtained at least once every 3 years. Contracts between MA organizations and institutional providers or suppliers generally require that the providers or suppliers notify the MA organization of any change in Medicare approval, state licensure and/or accreditation status.<sup>58</sup>

### **D. Notice of Reason for Not Including a Provider in a Network**

If an MA organization declines to include a particular provider or group of providers in its network, it must notify the affected provider, in writing, of the reason for the organization’s decision.<sup>59</sup> The MA organization is under no obligation to contract with a particular hospital or other provider, nor is there a process by which a hospital or other provider can appeal denial of inclusion in an MA organization’s network.

## **IV. Quality Improvement Programs**

Each MA organization is required to have an ongoing quality improvement program for each MA plan (except for MA private fee-for-service (“PFFS”) and MSA plans) that the MA organization offers.<sup>60</sup> As part of the ongoing quality improvement program, the plan must (1) have a chronic care improvement program (see below); (2) conduct quality improvement projects “that can be expected to have a favorable effect on health outcomes and enrollee satisfaction;” and (3) encourage its providers to participate in CMS and Department of Health and Human Services (“HHS”) quality improvement initiatives.<sup>61</sup> In certain instances, MA plans

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<sup>56</sup> Id.

<sup>57</sup> 42 C.F.R. § 422.204(b). See also MCM, Ch. 6, § 70.

<sup>58</sup> MCM, Ch. 6, § 70.

<sup>59</sup> Id. Ch. 6, § 60.1. While the CMS guidance uses the term “provider,” the notice obligation appears to apply to physicians and other health care professionals.

<sup>60</sup> Id. § 422.152(a).

<sup>61</sup> Id.

will ask their network providers to agree to assist them in their quality improvement efforts. As a result, it is important to understand the quality related requirements that apply to MA plans.

While the specific quality improvement requirements vary based on MA plan type, MA organizations offering any type of plan (including PFFS and MSA plans) must (1) maintain a health information system that collects, analyzes, and integrates the data necessary to implement its quality improvement program; (2) ensure that the information it receives from providers is reliable and complete; and (3) make all collected information available to CMS.<sup>62</sup> Additionally, the MA organization must, for each plan, have in effect a process for formal evaluation, at least annually, of the impact and effectiveness of its quality improvement program, and correct all problems that come to its attention through internal surveillance, complaints, or other mechanisms.<sup>63</sup> Compliance with these requirements will present particular challenges for MA plans operating primarily through non-network providers.

#### **A. Additional MA Coordinated Care Plan Requirements**

In addition to the above requirements, quality improvement projects for MA coordinated care plans (except MA Regional PPOs and certain local PPOs, as defined) must (1) follow written policies and procedures that reflect current standards of medical practice when processing requests for initial or continued authorization of services; (2) have in effect mechanisms to detect both under-utilization and over-utilization of services; and (3) measure and report performance under the MA plan using the measurement tools required by CMS.<sup>64</sup> The MA organization must provide CMS information on quality and outcome measures that will enable beneficiaries to compare health care coverage options and select among them.<sup>65</sup>

##### **1. Chronic Care Improvement Program**

The chronic care improvement program required by the regulations must include: (1) methods for identifying MA enrollees with multiple or sufficiently severe chronic conditions that would benefit from participating in the program; and (2) mechanisms for monitoring MA enrollees that are participating in the program.<sup>66</sup>

##### **2. Quality Improvement Projects**

Quality improvement projects are initiatives that focus on specified clinical and non-clinical areas and that involve: (1) measurement of performance; (2) system interventions, including the establishment or alteration of practice guidelines; (3) improving performance; and (4) systematic and periodic follow-up on the effect of the interventions.<sup>67</sup> For each quality

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<sup>62</sup> Id. § 422.152(f)(1).

<sup>63</sup> Id. § 422.152(f)(2) and (3).

<sup>64</sup> Id. § 422.152(b).

<sup>65</sup> Id.

<sup>66</sup> Id. § 422.152(c).

<sup>67</sup> Id. § 422.152(d)(1).

improvement project, the MA organization must assess performance under the plan using quality indicators that are (1) objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research; and (2) capable of measuring outcomes such as changes in health status, functional status and enrollee satisfaction, or valid proxies of those outcomes.<sup>68</sup> The performance assessment must be based on systematic ongoing collection and analysis of valid and reliable data.<sup>69</sup> Additionally, interventions must achieve demonstrable improvement.<sup>70</sup> Finally, the MA organization is required to report the status and results of each project to CMS, as requested.<sup>71</sup>

## **B. MA Regional Plan and MA Local PPO Plan Requirements<sup>72</sup>**

For MA regional plans and MA local PPO plans, the MA organization must (1) measure performance under the plan using standard measures required by CMS and report its performance to CMS; (2) evaluate the continuity and coordination of care furnished to enrollees; and (3) if using written protocols for utilization review, base those protocols on current standards of medical practice and have mechanisms to evaluate utilization of services and to inform enrollees and providers of services of the results of the evaluation.<sup>73</sup>

## **C. The Role Of Providers in Connection with Quality Improvement Programs and Data Reporting**

As noted, MA organizations are likely to ask their network providers to assist them with their quality improvement projects and related quality initiatives. Moreover, MA organizations may need to solicit information from providers in order to meet their quality improvement reporting obligations to CMS.<sup>74</sup> As a result, MA organizations can be expected to seek contract provisions requiring provider assistance with quality related initiatives. Such provisions might include the identification by providers of MA enrollees who might benefit from participation in targeted quality improvement projects. Similarly an MA organization may seek to develop a collaborative working relationship with a provider that has experience with specific programs that result in higher quality care or better clinical outcomes for patients.

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<sup>68</sup> Id. § 422.152(d)(2).

<sup>69</sup> Id. § 422.152(d)(3).

<sup>70</sup> Id. § 422.152(d)(4).

<sup>71</sup> Id. § 422.152(d)(5).

<sup>72</sup> For purposes of this rule, a local PPO means an MA plan that (1) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the MA organization; (2) provides reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers, and (3) is offered by an organization that is not licensed or organized under State law as a HMO. Id. § 422.152(e)(1).

<sup>73</sup> Id. § 422.152(e)(2).

<sup>74</sup> CMS has indicated that it will continue to require plans to collect, analyze and report using CMS outlined measurements or to participate in surveys such as the National Committee for Quality Assurance's Health Plan Employee Data and Information Set ("HEDIS"), the Health of Seniors ("HOS"), and/or the Consumer Assessment of Health Plans ("CAHPS") surveys. 70 Fed. Reg. at 4633.

## V. Provider Contracting

### A. **Affirmative Obligations**

#### 1. Contract Terms

MA organizations maintain ultimate responsibility for adhering to, and fully complying with, all terms and conditions of their MA contract with CMS.<sup>75</sup> CMS recognizes, however, that MA organizations frequently contract with other entities to assist them in fulfilling their contractual obligations in connection with the MA program. This is particularly true, for instance, with respect to the furnishing of health care services to enrollees since (more often than not) such services are furnished by “downstream” providers that contract with the MA organization. Accordingly, the MA regulations require that contracts between MA organizations and providers of health care contain certain required provisions.<sup>76</sup> Specifically, MA organizations must include provisions in their contracts with related entities, contractors, or subcontractors that address the following:

1. The HHS, the Comptroller General, and their designees have the right to inspect, evaluate, and audit any of the provider’s pertinent contracts, books, documents, papers, and records involving transactions related to the MA contract for a period of 6 years from the final date of the contract period or from the date of completion of any audit, whichever is later.<sup>77</sup>
2. Providers shall not hold enrollees liable for payment of any fees that are the obligation of the MA organization.<sup>78</sup>
3. The MA organization may only delegate activities or functions to a provider pursuant to written agreements that meet the following requirements:<sup>79</sup>
  - a. specify the relevant delegated activities and reporting responsibilities;
  - b. either provide for revocation of the delegation activities and/or reporting requirements or specify other remedies in instances where CMS or the MA organization determines that such parties have not performed satisfactorily;
  - c. specify that the performance of the parties will be monitored by the MA organization on an ongoing basis;

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<sup>75</sup> Id. § 422.504(i)(1).

<sup>76</sup> Id. § 422.504(i).

<sup>77</sup> Id. § 422.504(i)(2).

<sup>78</sup> Id. § 422.504(i)(3)(i). Such provision will apply, without limitation, to insolvency of the MA organization or contract breach. MCM, Ch. 11, § 100.4.

<sup>79</sup> 42 C.F.R. § 422.504(i)(3).

- d. specify that either (1) the credentials of medical professionals affiliated with the party or parties will be reviewed by the MA organization; or (2) the credentialing process will be reviewed and approved by the MA organization and the MA organization will audit the credentialing process on an ongoing basis; and
  - e. specify that the provider must comply with all applicable Medicare laws, regulations, and CMS instructions.<sup>80</sup>
4. Services or other activity performed by the provider in accordance with the contract shall be consistent and comply with the MA organization's contractual obligations.<sup>81</sup>
  5. Provider shall safeguard beneficiary privacy and confidentiality and assure accuracy of beneficiary health records.<sup>82</sup>
  6. MA organization shall pay the provider pursuant to "prompt payment" terms agreed upon by the MA organization and the provider.<sup>83</sup>
  7. Provider shall comply with the MA organization's policies and procedures.<sup>84</sup>

Additional requirements may apply if the MA organization delegates certain administrative or other functions to the provider.<sup>85</sup> Some notable examples include issuance of the Notice of Discharge and Medicare Appeal Rights ("NODMAR") and notice concerning non-coverage of inpatient hospital care.<sup>86</sup>

## 2. MA Organization Policies and Procedures

CMS has determined that certain items do not need to be specifically included in the provider contract, but must be included in the MA organization's policies and procedures.<sup>87</sup> There are thirty-two items that are incorporated by reference into the provider contract in this way. In essence, this approach reflects CMS' recognition that MA organizations need the direct cooperation and support of their network providers to comply with many of the MA program requirements.

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<sup>80</sup> Id. § 422.504(i)(4).

<sup>81</sup> Id. § 422.504(i)(3).

<sup>82</sup> Id. § 422.118; MCM, Ch. 11, § 100.4.

<sup>83</sup> 42 C.F.R. § 422.520(b).

<sup>84</sup> MCM, Ch. 11, § 100.4.

<sup>85</sup> See id. § 100.5.

<sup>86</sup> See 42 C.F.R. § 422.620.

<sup>87</sup> MCM, Ch. 11, § 100.4. Such policies and procedures are usually set forth in the MA organization's policy manual.

The MCM contains a helpful table summarizing the various regulatory requirements that must be included in the policies and procedures.<sup>88</sup> We reference a few of the relevant requirements here.

1. Providers must safeguard the privacy of patient information and maintain records in a timely and accurate fashion.
2. Providers may not discriminate against MA plan enrollees on the basis of health status.
3. MA plan services must be available 24 hours per day, 7 days per week, when medically necessary.<sup>89</sup>
4. Services must be provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds.<sup>90</sup>
5. Providers must ensure that enrollees are informed of specific health care needs that require follow-up care and receive, as appropriate, training in self-care and other measures they may take to promote their own health.<sup>91</sup>
6. Providers must document in a prominent place in the medical record if the MA plan enrollee has executed an Advance Directive.
7. Provider must acknowledge that they are subject to laws applicable to recipients of Federal funds, including the False Claims Act and the anti-kickback statute.<sup>92</sup>
8. Providers must certify the completeness and truthfulness of all encounter data submitted to the MA organization.
9. Providers must cooperate with quality review and improvement organizations.<sup>93</sup>
10. Providers must not employ or contract with individuals or entities that are excluded from participation in Medicare.
11. Providers must furnish care in a manner consistent with professionally recognized standards of care.

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<sup>88</sup> Given the importance of these requirements, we provide a link to the relevant MCM chapter here: <http://www.cms.hhs.gov/manuals/downloads/mc86c11.pdf>.

<sup>89</sup> MCM, Ch. 11, § 100.4; see 42 C.F.R. § 422.112(a)(7).

<sup>90</sup> MCM, Ch. 11, § 100.4; see 42 C.F.R. § 422.112(a)(8).

<sup>91</sup> MCM, Ch. 11, § 100.4; see 42 C.F.R. § 422.112(b)(5).

<sup>92</sup> MCM, Ch. 11, § 100.4; see 42 C.F.R. § 422.504(l)(1) and (2).

<sup>93</sup> MCM, Ch. 11, § 100.4.

## **B. Prohibited Provisions**

MA organizations may not contract or otherwise provide, directly or indirectly, for any individual, group of physicians, health care professional, provider of services, or any entity providing health care services, to indemnify the MA organization against any civil liability for damage caused to an enrollee as a result of the MA organization's denial of medically necessary care.<sup>94</sup>

## **VI. Provider Grievances and Appeals**<sup>95</sup>

The subject of Grievances and Appeals was discussed at some length in the Primer for Session 1: The Basics.<sup>96</sup> Much of the discussion there focused on the rights of MA enrollees. A few points are worth making here. First, any provider that furnishes, or intends to furnish, services to an MA plan enrollee may request an organization determination from the MA plan regarding the benefits the enrollee is entitled to receive under an MA plan.<sup>97</sup> Any physician, whether affiliated with the MA organization or not, may request an expedited determination.<sup>98</sup> In some limited instances, providers may seek review of an adverse organization determination.<sup>99</sup> However, contract providers do not have appeal rights under the MA regulations or CMS policy.<sup>100</sup> Thus, contract providers should seek a dispute resolution mechanism in their agreement with the MA organization.

## **VII. Considerations in Hospital Contracting with MA Organizations**

Hospitals, as well as other providers, entering into contracts with MA organizations need to be thoughtful in identifying the terms and positions that should be addressed during the contract negotiation and, ultimately, in the written agreement. While the MA regulations and CMS Managed Care Manuals provide some specific provisions which must be incorporated in contracts between MA organizations and their contracted providers, other important provisions are left to the discretion of the parties.

A rule of thumb for providers may be to approach the MA negotiating and contracting process as if it were for a commercial managed care contract. Every issue that a hospital would address in contracting with a commercial managed care organization should be considered and,

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<sup>94</sup> 42 C.F.R. § 422.212.

<sup>95</sup> See Session I Primer for an explanation of the procedures and timeframe for grievances, appeals, and organization determinations.

<sup>96</sup> See Session I Primer, at 21. Note in particular the discussion of appeals of adverse organization decisions as they relate to denials for payment of services based on coverage or medical necessity determinations.

<sup>97</sup> Id. § 422.566(a) and (c)(1)(ii).

<sup>98</sup> Id. § 422.570(a).

<sup>99</sup> See id. § 422.574(b) and 422.578.

<sup>100</sup> MCM, Ch. 13, §70.1.

as appropriate, included in the contract with the MA organization.<sup>101</sup> Providers should be mindful, however, that Congress significantly expanded the scope of Federal preemption of State law under the MA program.<sup>102</sup> As a result, State law protections that would apply in other contexts (e.g., prompt payment rules) may not be available, unless specifically agreed to by the parties in their contract.<sup>103</sup>

A partial list of subjects that could be addressed in the MA contract includes:

1. Prompt payment policies setting specific standards, time frames, and late payment penalties;
2. Payment of administrative costs when the plan delegates to the provider functions that are the plan's responsibility (i.e., NODMAR and Medicare Secondary Payer functions);
3. Procedures for timely notification (via email or fax) to specific hospital officials when coverage for care of a particular patient is being discontinued;
4. Timely notification of changes in MA organization policies and procedures (and a delayed effective date, where appropriate consistent with MA program requirements);
5. A mechanism, perhaps involving an independent third party, for retrospective review of denials of payment for provided services;
6. Procedures regarding scheduling of visits by MA organization staff, and proper identification of such staff, when the MA organization needs to access patient records;
7. Provisions governing the MA organization's right to audit (how often and who will pay);
8. The MA organization's agreement to arrange for continuation of health care coverage for enrollees who are hospitalized upon MA organization insolvency or other conditions (as required by MA program rules) through insurance or other arrangements acceptable to CMS; and<sup>104</sup>

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<sup>101</sup> A comprehensive treatment of issues that arise in provider and managed care plan contracting is beyond the scope of this primer. However, the American Health Lawyers Association ("AHLA") has excellent materials on this subject. A list of AHLA publications can be found on its website: <http://www.healthlawyers.org/>.

<sup>102</sup> 42 C.F.R. § 422.402.

<sup>103</sup> MA organizations may not, however, agree to contract provisions that contradict the MA program rules.

<sup>104</sup> MA organizations frequently ask hospitals to agree to provide such continuation coverage. The MA regulations, however, state that MA organizations may satisfy their obligation to CMS to provide such coverage to enrollees through (a) contractual arrangements (e.g., provider contracts), (b) insurance acceptable to CMS, (iii) financial reserves acceptable to CMS, or (iv) other arrangements acceptable to CMS. *Id.* § 422.504(g)(2).

9. Indemnification protection.

**VIII. Concluding Remarks**

The MA regulations impose significant new administrative and other requirements on providers of health care, both directly and indirectly. They also establish the framework for negotiations with the MA organizations. As a general matter, it is important for hospitals to compare proposed contracts against the MA program rules (to identify which provisions are and are not required by the regulations) and against the terms in their standard commercial contracts (to identify topics for inclusion and to determine whether the MA organization's proposal is more or less favorable than the standard commercial terms.). In determining whether a particular contract is acceptable, hospitals must factor in the additional administrative costs associated with being an MA plan provider (e.g., costs associated with quality improvement initiatives and any unique data reporting obligations). Finally, hospitals must be mindful that state law protections may not be available in the MA context and seek to include similar protections in the terms of their written agreements with MA organizations.

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