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Module 10

STUDY GUIDE

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Federal Register

The Federal Register (the daily journal of the Federal government) is published every business day by the National Archives and Records Administration (NARA)'s Office of the Federal Register (OFR), who also prepares it.

The Federal Register contains:

- Federal agency regulations
- Proposed Rules and Notices of interest to the public
- Executive orders
- Proclamations
- Other Presidential documents

The OFR prepares the Federal Register for publication in partnership with the Government Publishing Office (GPO). GPO distributes the Federal Register in paper, on microfiche, and online as PDF files. You can also access our unofficial version of the Federal Register at www.federalregister.gov.

Why should I read the Federal Register?

The Federal Register informs citizens of their rights and obligations and provides access to a wide range of Federal benefits and opportunities for funding.

Who uses the Federal Register?

Anyone:

- who needs to know about the day-to-day operations of the Federal Government
- whose business is regulated by a Federal agency
- who is an attorney practicing before a regulatory agency
- who attends public hearings or meetings or applies for grants
- who is concerned with Government actions that affect the environment, health care, financial services, exports, education, or other major public policy issues

Module 10 | Things to Know PMBi Study Guide

Where is the Federal Register available?

- To read or purchase copies of the Federal Register:
- Visit GPO's Govinfo.gov or Federalregister.gov, for free online access to Federal Register publications
- Visit any Federal Depository Library for reference copies of Federal Register publications
- Visit GPO's U.S. Government Bookstore
- Purchase by phone or fax:
 - Telephone 202-512-1800, M-F, 8 a.m. to 4 p.m.
 - Fax orders and inquiries to 202-512-2250 (anytime)
- Purchase by mail:
 - Superintendent of Documents
 - P.O. Box 371954
 - Pittsburgh, PA 15250-7954
- Send E-mail questions and comments on Federal Register services to: fedreg.info@nara.gov

A Guide to the Rulemaking Process

Prepared by the Office of the Federal Register

Before the Proposed Rule

What gives agencies the authority to issue regulations?

Agencies get their authority to issue regulations from laws (statutes) enacted by Congress. In some cases, the President may delegate existing Presidential authority to an agency. Typically, when Congress passes a law to create an agency, it grants that agency general authority to regulate certain activities within our society. Congress may also pass a law that more specifically directs an agency to solve a particular problem or accomplish a certain goal.

An agency must not take action that goes beyond its statutory authority or violates the Constitution. Agencies must follow an open public process when they issue regulations, according to the Administrative Procedure Act (APA). This includes publishing a statement of rulemaking authority in the Federal Register for all proposed and final rules.

How does an agency decide to begin rulemaking?

Congress may pass a law that directs an agency to take action on a certain subject and set a schedule for the agency to follow in issuing rules. More often, an agency surveys its area of legal responsibility, and then decides which issues or goals have priority for rulemaking.

These are a few of the many factors that an agency may consider:

Module 10 | Things to Know PMBi Study Guide

- New technologies or new data on existing issues;
- Concerns arising from accidents or various problems affecting society;
- Recommendations from Congressional committees or federal advisory committees;
- Petitions from interest groups, corporations, and members of the public;
- Lawsuits filed by interest groups, corporations, States, and members of the public;
- Presidential directives;
- “Prompt letters” from the Office of Management and Budget (OMB);
- Requests from other agencies;
- Studies and recommendations of agency staff.

When can the public learn that an agency plans to start a rulemaking?

Agencies are required to publish a “Regulatory Plan” once a year in the fall and an “Agenda of Regulatory and Deregulatory Actions” in the spring and fall. The Regulatory Plan and the Regulatory Agenda are often referred to as the “Unified Agenda.” The Unified Agenda is how agencies announce future rulemaking activities update the public on pending and completed regulatory actions.

The Unified Agenda is posted on RegInfo.gov and Regulations.gov. Agencies also publish most of this material (their regulatory plans) in the Federal Register. The Federal Register version and a separate Unified Agenda collection are available on the Government Printing Office’s (GPO) Federal Digital system (FDsys.gov).

How does an agency involve the public in developing a proposed rule?

An agency may take some preliminary steps before issuing a proposed rule. They gather information through unstructured processes and informal conversations with people and organizations interested in the issues. If an agency receives a “Petition for Rulemaking” from a member of the public, it may decide to announce the petition in the Federal Register and accept public comments on the issue.

An agency that is in the preliminary stages of rulemaking may publish an “Advance Notice of Proposed Rulemaking” in the Federal Register to get more information. The Advance Notice is a formal invitation to participate in shaping the proposed rule and starts the notice-and-comment process in motion.

Anyone interested (individuals and groups) may respond to the Advance Notice by submitting comments aimed at developing and improving the draft proposal or by recommending against issuing a rule. Some agencies develop proposed rules through a negotiated rulemaking. In this process, an agency invites members of interested groups to meetings where they attempt to reach a consensus on the terms of the proposed rule. If the participants reach agreement, the agency may endorse their ideas and use them as the basis for the proposed rule.

What is the role of the President in developing a proposed rule?

Before a proposed rule is published in the Federal Register for public comment, the President, as head of the Executive branch, may take the opportunity to review the rule. The President is assisted by the Office of Information & Regulatory Affairs (OIRA), which analyzes draft proposed rules when they are “significant” due

Module 10 | Things to Know PMBi Study Guide

to economic effects or because they raise important policy issues. For significant rules, the agency must estimate the costs and benefits of the rule and consider alternate solutions.

If the proposed rule requires the public to provide information to the government, the agency must estimate the paperwork burden on the public and obtain permission to proceed from OIRA. In addition, the agency may be required to analyze a proposed rule's impact on: small businesses; state, local and tribal governments; families; federalism. It may also need to analyze issues of just compensation and unfunded mandates.

The Proposed Rule

What is the purpose of the proposed rule?

The proposed rule, or Notice of Proposed Rulemaking (NPRM), is the official document that announces and explains the agency's plan to address a problem or accomplish a goal. All proposed rules must be published in the Federal Register to notify the public and to give them an opportunity to submit comments. The proposed rule and the public comments received on it form the basis of the final rule.

How is the proposed rule structured?

Proposed rules have preambles which contain a summary, date and contact information, and supplementary information. A proposed rule begins with a "Summary" of the issues and actions under consideration; it also states why the rule is necessary. Under the "Dates" and "Addresses" captions, the agency invites everyone to comment on the proposed rule, sets a date for comments to be submitted, and specifies various methods for conveying comments. Many agencies give several options for submitting comments, including U.S. mail, private courier, email, and the official federal electronic comment portal: Regulations.gov.

In the "Supplementary Information" portion, the agency discusses the merits of the proposed solution, cites important data and other information used to develop the action, and details its choices and reasoning. The agency must also identify the legal authority for issuing the rule.

Following the preamble, the agency usually publishes the regulatory text of the proposal in full. The regulatory text sets out amendments to the standing body of law in the Code of Federal Regulations. If the amendments are not set out in full text, the agency must describe the proposed action in a narrative form.

What is the time period for the public to submit comments?

In general, agencies will specify a comment period ranging from 30 to 60 days in the "Dates" section of the Federal Register document, but the time period can vary. For complex rulemakings, agencies may provide for longer time periods, such as 180 days or more. Agencies may also use shorter comment periods when that can be justified.

Module 10 | Things to Know PMBi Study Guide

Members of the public may request that the agency allow more time to submit comments, and agencies may consider late-filed comments, if their decision-making schedule permits it.

Commentors should be aware that agencies generally are not legally required to consider late- filed comments. Agencies usually provide information in the proposed rule and/or their procedural rules indicating whether they will consider late-filed comments.

Why do agencies re-open comments or issue multiple proposed rules?

An agency may extend or re-open a comment period when it is not satisfied that it has enough high quality comments or when the public comments make a good case for adding more time.

Similarly, an agency may find that people have raised new issues in their comments that were not discussed in the initial proposed rule. As new issues or additional complexity arises, the agency may publish a series of proposed rules in the Federal Register.

Do agencies have additional options for gathering public comments?

During the comment period, an agency may also hold public hearings where people can make statements and submit data. Some agencies operate under laws that require rulemaking hearings. Others may hold public meetings to collect more information or to help affected groups get a better understanding of the proposed rule. Many agencies are beginning to use webcasts and interactive Internet sessions to broaden the audience attending public meetings.

After the comment period closes, an agency may establish a second period for reply comments (comments that respond to prior comments). A reply period is not required by law. The reply comment period enables people to respond to comments that agencies received at the end of comment period, creating more of a public dialog.

Why should you consider submitting electronic comments?

Most agencies now prefer to receive comments electronically so that your input on a proposed rule or other document is more easily available to the public. Having electronic data helps agencies organize the comments by subject or in other ways to help the public and the agency make more effective use of them.

You can submit electronic comments to the agency docket site by following the instructions in the Federal Register. Many of the proposed rules and other documents on this site display a special button for submitting comments directly to the official electronic docket. For information on using the federal eRulemaking portal to submit comments, go to the Regulations.gov “Help” pages on submitting a comment.

Module 10 | Things to Know PMBi Study Guide

Before the Final Rule

How do public comments affect the final rule?

The notice-and-comment process enables anyone to submit a comment on any part of the proposed rule. This process is not like a ballot initiative or an up-or-down vote in a legislature. An agency is not permitted to base its final rule on the number of comments in support of the rule over those in opposition to it. At the end of the process, the agency must base its reasoning and conclusions on the rulemaking record, consisting of the comments, scientific data, expert opinions, and facts accumulated during the pre-rule and proposed rule stages.

To move forward with a final rule, the agency must conclude that its proposed solution will help accomplish the goals or solve the problems identified. It must also consider whether alternate solutions would be more effective or cost less.

If the rulemaking record contains persuasive new data or policy arguments, or poses difficult questions or criticisms, the agency may decide to terminate the rulemaking. Or, the agency may decide to continue the rulemaking but change aspects of the rule to reflect these new issues. If the changes are major, the agency may publish a supplemental proposed rule. If the changes are minor, or a logical outgrowth of the issues and solutions discussed in the proposed rules, the agency may proceed with a final rule.

What is the role of the President in developing a final rule?

In the same way that the President and the Office of Information & Regulatory Affairs (OIRA) review draft proposed rules prior to publication, the President and OIRA analyze draft final rules when they are “significant” due to economic effects or because they raise important policy issues. The Presidential level review takes place before the final rule is published in the Federal Register. OIRA’s final analysis of estimated costs and benefits may take into consideration any comments and alternate solutions suggested in public comments.

Agencies may also use this review and analysis phase to consult with other agencies who share responsibility for issues covered by the rule. In some cases, interagency review is mandatory.

The Final Rule

How is the final rule structured?

Final rules also have preambles, including the summary, effective date, and supplementary information. The final rule published in the Federal Register begins with a “Summary” of the societal problems and regulatory goals and explains why the rule is necessary.

Module 10 | Things to Know PMBi Study Guide

Every final rule must have an “Effective Date.” However, any portions that are subject to later approval under the Paperwork Reduction Act or are subject to Congressional approval may be excepted from that effective date. The “ates” caption in the Federal Register may also contain compliance or applicability dates.

The agency must state the “basis and purpose” of the rule in the “Supplementary Information” part of the preamble. This statement sets out the goals or problems the rule addresses, describes the facts and data the agency relies on, responds to major criticisms in the proposed rule comments, and explains why the agency did not choose other alternatives.

The agency must identify its legal authority for issuing the rule and publish the regulatory text in full. The regulatory text sets out amendments to the Code of Federal Regulations (CFR).

Each amendment begins with instructions for changing the CFR.

When do final rules go into effect?

When an agency publishes a final rule, generally the rule is effective no less than thirty days after the date of publication in the Federal Register. If the agency wants to make the rule effective sooner, it must cite “good cause” (persuasive reasons) as to why this is in the public interest.

Significant rules (defined by Executive Order 12866) and major rules (defined by the Small Business Regulatory Enforcement Fairness Act) are required to have a 60 day delayed effective date.

Can an agency issue a final rule without a publishing a proposed rule?

Yes, the Administrative Procedure Act (APA) permits agencies to finalize some rules without first publishing a proposed rule in the Federal Register. This exception is limited to cases where the agency has “good cause” to find that the notice-and-comment process would be “impracticable, unnecessary, or contrary to the public interest.” These situations may include emergencies where problems must be addressed immediately to avert threats to public health and safety, minor technical amendments and corrections where there is no substantive issue, and some instances where an agency has no discretion to propose a rule because Congress has already directed a specific regulatory outcome in a law. The agency must state its reasoning for finding good cause in the preamble of the final rule published in the Federal Register.

There are other exceptions to conventional notice-and-comment rulemaking. An agency may go straight to final rulemaking without a proposed rule when they issue internal agency procedures, rules that affect only federal employees, and rules that manage federal property and real estate. Even these types of rules can be subject to proposed rulemaking because of a special statutory requirement or because an internal agency rule also has a substantial effect on the public.

Agencies can also issue and enforce rules by using “actual notice,” which requires direct notification of all affected persons and entities. Because it is difficult to pinpoint every person and entity affected by a rulemaking, this option is used mostly for rules that have a very narrow effect on known or readily definable persons or corporations.

Module 10 | Things to Know PMBi Study Guide

What are interim final rules & direct final rules?

Interim Final Rule: When an agency finds that it has good cause to issue a final rule without first publishing a proposed rule, it often characterizes the rule as an “interim final rule,” or “interim rule.” This type of rule becomes effective immediately upon publication. In most cases, the agency stipulates that it will alter the interim rule if warranted by public comments. If the agency decides not to make changes to the interim rule, it generally will publish a brief final rule in the Federal Register confirming that decision.

Direct Final Rule: When an agency decides that a proposed rule is unnecessary because it would only relate to routine or uncontroversial matters, it may publish a direct final rule in the Federal Register. In a direct final rule, the agency states that the rule will go into effect on a certain date, unless it gets substantive adverse comments during the comment period. An agency may finalize this process by publishing in the Federal Register a confirmation that it received no adverse comments. If adverse comments are submitted, the agency is required to withdraw the direct final rule before the effective date. The agency may re-start the process by publishing a conventional proposed rule or decide to end the rulemaking process entirely.

After the Final Rule

How are final rules integrated into the Code of Federal Regulations?

Agencies must publish the changes to the Code of Federal Regulations (CFR) in the final rule, instructing how amendments add, revise, remove, or re-designate regulatory text. The CFR contains all of the generally applicable rules of the Federal government with current or future effect.

On the day a final rule is published in the Federal Register, Office of the Federal Register and GPO staff begin processing the material for codification into the CFR. Rules that are immediately effective are integrated into the “Electronic Code of Federal Regulations” (e-CFR) database (ecfr.gpoaccess.gov). Rules with delayed effective dates are placed in amendment files and linked from the main e-CFR database. The e-CFR is an unofficial, but authoritative editorial compilation published by the Office of the Federal Register and GPO. Users can check the update status of the e-CFR by consulting the home page.

The official annual editions of the CFR are assembled from the material published in the e-CFR. Each of the 50 subject matter titles are republished each year on a staggered, quarterly basis, and appear in print and online (<http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR>).

How is the Congress involved in reviewing final rules?

Under the Small Business Regulatory Enforcement Fairness Act (also known as the Congressional Review Act), new final rules must be sent to Congress and the Government Accountability Office for review before they can take effect. “Major rules” (ones that are economically significant and require OIRA review) must be made effective at least 60 days after the date of publication in the Federal Register, allowing time for Congressional review. In emergency situations, a major rule can be made effective before 60 days.

Module 10 | Things to Know PMBi Study Guide

If the House and Senate pass a resolution of disapproval and the President signs it (or if both houses override a presidential veto), the rule becomes void and cannot be republished by an agency in the same form without Congressional approval. Since 1996, when this process started, Congress has disapproved only one rule.

Congress may also exercise its oversight in other ways, by holding hearings and posing questions to agency heads, by enacting new legislation, or by imposing funding restrictions.

Does the regulatory process continue after rules are published?

The regulatory process enters the compliance, interpretation, and review phase after a final rule is published. Individuals and industries affected by a rule, and the agency compliance officers and inspectors who must enforce a rule, may need guidance to better understand the regulatory requirements. Agencies may write compliance materials and technical assistance manuals to distribute to the public. These guidance materials may be posted on a website or published in the Federal Register as interpretive rules. See more about interpretive rules and policy statements below.

Based on its experience in enforcing a rule, an agency may decide to change a rule, remove it from the CFR entirely, or let it stand. A law or a Presidential directive may require a formal review process every few years. An agency may undertake a review based on a petition from the public. Its own experts may also begin a review process when conditions change and rules seem outdated. If an agency decides to amend or revoke a rule, it must use the notice-and-comment process to make the change.

What are interpretive rules and policy statements?

Interpretive rules, policy statements, and other guidance documents may be issued anytime after a final rule is published to help the public understand to how a regulation applies to them and affects their interests. An agency may explain how it interprets an existing regulation or statute, how a rule may apply in a given instance, and what things a person or corporation must do to comply.

There is a key distinction between an interpretive rule and a final “legislative” or “substantive” rule. The interpretive rule or policy statement must not set new legal standards or impose new requirements. Guidance documents do not contain amendments to the CFR and are not subject to the notice and comment process. But in some cases, agencies choose to request comments on interpretive rules and other guidance documents to improve the quality and clarity of the material. Interpretive rules and policy statements that have broad applicability are often published in the Federal Register, but some may only appear on agency websites.

When do the courts get involved in rulemaking?

Individuals and corporate entities may go into the courts to make a claim that they have been, or will be, damaged or adversely affected in some manner by a regulation. The reviewing court can consider whether a rule: is unconstitutional; goes beyond the agency’s legal authority; was made without following the notice-and-comment process required by the Administrative Procedure Act or other law; or was arbitrary, capricious, or an abuse of discretion. An agency head can also be sued for failing to act in a timely manner in certain cases.

Module 10 | Things to Know PMBi Study Guide

If a court sets aside (vacates) all or part of a rule, it usually sends the rule back to the agency to correct the deficiencies. The agency may have to reopen the comment period, publish a new statement of basis and purpose in the Federal Register to explain and justify its decisions, or re-start the rulemaking process from the beginning by issuing a new proposed rule.

PEPPERReport

What is PEPPER?

The Program for Evaluating Payment Patterns Electronic Report (PEPPER) is a Microsoft Excel file summarizing provider-specific Medicare data statistics for target areas often associated with Medicare improper payments due to billing, DRG coding and/or admission necessity issues. Target areas are determined by the Centers for Medicare & Medicaid Services (CMS).

PEPPER facilitates the prioritization of areas on which a hospital or facility may want to focus auditing and monitoring efforts. Hospitals and facilities are encouraged to conduct regular audits to ensure that medical necessity for admission and treatment is documented and that bills submitted for Medicare services are correct.

PEPPER can be used to review three years of data statistics for each of the CMS target areas, comparing performance to that of other hospitals or facilities in the nation, specific Medicare Administrative Contractor (MAC) jurisdiction and state. PEPPER can also be used to compare data statistics over time to identify changes in billing practices, pinpoint areas in need of auditing and monitoring, identify potential DRG under- or over-coding problems and identify target areas where length of stay is increasing. PEPPER can help hospitals and facilities achieve CMS' goal of reducing and preventing improper payments.

Due to data restrictions established by CMS, hospital/facility data are not displayed for a time period in PEPPER for any given target area if the numerator or denominator count is less than 11. This data restriction may result in a small number of hospitals and facilities either not receiving a PEPPER (numerator count is less than 11 for all time periods, all target areas) or their PEPPER may not display data in some time periods for some target areas.

TMF Health Quality Institute, under contract with CMS, began providing PEPPER to all providers in the nation in January 2010.

PEPPER was developed for short-term acute care hospitals in 2002 by TMF Health Quality Institute in support of CMS' Hospital Payment Monitoring Program. State Quality Improvement Organizations (QIOs) began distributing PEPPER to the short-term acute care hospitals in their state in 2003. PEPPER was developed for long-term acute care hospitals in 2005. In 2008 QIOs were no longer responsible for working to reduce the improper Medicare fee-for-service error rate, and the Hospital Payment Monitoring Program ended. In 2009 TMF was contracted by CMS through the Office of Financial Management Provider Compliance Group to develop, produce and distribute PEPPERS to all short- and long-term hospitals in the nation. The first release

Module 10 | Things to Know PMBi Study Guide

under this contract was completed in early 2010. Since then TMF, at CMS' direction, has developed additional types of PEPPER for other providers.

In 2011 PEPPER was developed for critical access hospitals, inpatient psychiatric facilities and inpatient rehabilitation facilities.

In 2012 PEPPER was developed for hospices and partial hospitalization programs.

In 2013 PEPPER was developed for skilled nursing facilities.

In 2015 a PEPPER was developed for home health agencies.

View the PEPPER distribution schedule and information on how to get your PEPPER.

Who benefits from PEPPER?

CEOS AND ADMINISTRATORS

Use PEPPER to:

- Access tables and graphs displaying billing activity over time in comparison with other hospitals or facilities
- Review hospital- or facility-specific data and comparative target area statistics for the state, jurisdiction, and nation
- Track and trend administrative data statistics to identify changes in billing practices and Medicare reimbursement for CMS target areas

CHIEF FINANCIAL OFFICERS

Use PEPPER to:

- Identify areas of potential overpayments and underpayments
- Identify DRGs with a high proportion of short-stay outliers (for long-term care hospitals)
- Compare length of stay data to length of stay data for the jurisdiction
- Assess Medicare reimbursement for target areas, track and trend over time

COMPLIANCE OFFICERS

Use PEPPER to:

- Review hospital- or facility-specific data statistics for target areas identified by CMS as at high risk for improper payment
- Identify areas of potential overpayments and underpayments
- Help prioritize areas for compliance auditing and monitoring
- Access data tables and graphs displaying billing activity over time in comparison with other hospitals or facilities

Module 10 | Things to Know PMBi Study Guide

UTILIZATION REVIEW/QUALITY IMPROVEMENT STAFF

Use PEPPER to:

- Identify areas that may be in need of closer study to determine admission necessity or whether a procedure or treatment was performed in the appropriate setting
- Monitor readmission rates to assist in identifying opportunities for improvement related to case management, discharge planning and quality of care
- Identify target areas where the average length of stay is increasing (or decreasing, in the case of long-term care hospitals)
- Aid efforts to improve medical record documentation

HEALTH INFORMATION MANAGEMENT STAFF

Use PEPPER to:

- Identify potential DRG over-coding and under-coding
- Identify DRGs that are problematic on which the hospital or facility may want to focus auditing and monitoring
- Access tables and graphs displaying billing activity over time in comparison with other hospitals or facilities, which can be used for educational training activities
- Prioritize areas for coding compliance auditing and monitoring
- Aid efforts to improve medical record documentation

HHCAPS

Overview

The Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Home Health Care Survey, hereafter referred to as the "Home Health Care CAHPS Survey" is designed to measure the experiences of people receiving home health care from Medicare-certified home health care agencies. The survey is designed to meet the following three broad goals:

To produce comparable data on the patient's perspective that allows objective and meaningful comparisons between home health agencies on domains that are important to consumers.

Public reporting of survey results will create incentives for agencies to improve their quality of care.

Public reporting will enhance public accountability in health care by increasing the transparency of the quality of care provided in return for public investment.

Development of the Home Health Care CAHPS Survey

In November 2002, the Quality Initiative was launched to ensure quality health care for all Americans through accountability and public disclosure. The initiative aims to (a) empower Americans with quality of care

Module 10 | Things to Know PMBi Study Guide

information to help them make more informed decisions about their health care, and (b) stimulate and support providers and clinicians to improve the quality of health care. The Quality Initiative was launched nationally in November 2002 for nursing homes (the Nursing Home Quality Initiative), and expanded in 2003 to the nation's hospitals and home health care agencies. Consumers can view these measures on Home Health Compare at www.medicare.gov.

On September 25, 2006, the Agency for Healthcare Research and Quality (AHRQ) published a call in the Federal Register for survey items or measures representing areas of quality home health care that are viewed as important to consumers, their families, and intermediaries and initiated a review of existing literature in the area. AHRQ developed a draft survey instrument after several rounds of cognitive testing. A field test was conducted in 2008 with 34 home health agencies to test the psychometric properties of the survey and finalize its content. A final Home Health Care CAHPS Survey was developed in the summer of 2008. The Survey was endorsed by the National Quality Forum in March 2009 and approved by the United States Office of Management and Budget in July 2009. For more information on the CAHPS family of surveys, please visit <http://www.cahps.ahrq.gov>.

National Implementation and Public Reporting

The national implementation of the HHCAHPS Survey began in October 2009 with agencies participating on a voluntary basis prior to when quality reporting requirements for the home health annual payment update (APU) began in the third quarter of calendar year 2010. The Centers for Medicare & Medicaid Services (CMS) began publicly reporting results from the HHCAHPS Survey on Home Health Compare on the Medicare.gov Web site in April of 2012.

As described in the 2010 Home Health Prospective Payment System (HHPPS) Final Rule (42 CFR 409, 424, 484 [10 November 2009]), HHCAHPS was linked to the quality reporting requirement for the CY 2012 annual payment update (APU). As described in the 2011 HHPPS Final Rule (42 CFR Parts 409, 418, 424 et al. [17 November, 2010]), quality reporting for the 2013 APU was required of all Medicare-certified home health agencies who served 60 or more patients between April 1, 2010 and March 31, 2011 who met survey-eligibility criteria. Medicare-certified home health agencies that served 59 or fewer patients between April 1, 2010 and March 31, 2011 who met survey-eligibility criteria were able to apply for exemption from participating in the HHCAHPS Survey.

To receive the annual payment update (APU) for any given year, home health agencies that do not qualify for an exemption from participating in the HHCAHPS Survey for the specified APU must contract with an approved HHCAHPS Survey vendor and administer the survey on an ongoing (monthly) basis and submit HHCAHPS Survey data to the HHCAHPS Data Center on a quarterly basis. More information about the HHCAHPS Survey and participation requirements is available in the "HHA Responsibilities" document. To apply for an exemption, HHAs must count and report to CMS the number of patients served during the specified 12-month period via the online HHCAHPS Survey Participation Exemption Request Form, which is available on this website under the "For HHAs" tab.

Module 10 | Things to Know PMBi Study Guide

CMS & Telemedicine

The Centers for Medicare & Medicaid Services (CMS) released its 2,475-page 2020 Medicare Physician Fee Schedule Final Rule (Final Rule) November 1, 2019. Noting that only 9% of Medicare fee-for-service beneficiaries presently receive ambulatory care management services, CMS is making several important changes to expand access to these services. The following insight summarizes new Medicare reimbursement rules for transitional care management, chronic care management, principal care management, and remote patient monitoring.

TCM – Transitional Care Management

For detailed information on TCM reimbursement rules, view PYA’s white paper, *Providing and Billing Medicare for Transitional Care Management*.

According to CMS, a recent analysis of TCM claims data determined that “beneficiaries who receive TCM services demonstrated reduced readmission rates, lower mortality, and decreased healthcare costs.” The same analysis, however, “found that use of TCM services is low when compared to the number of Medicare beneficiaries with eligible discharges.” In fact, providers submitted only 1.3 million claims for TCM in 2018 compared to approximately 9.5 million Medicare hospital discharges that year.

To increase TCM utilization, CMS is reducing the administrative burden associated with billing TCM services. Specifically, CMS is eliminating the prohibition on a practitioner billing for certain services furnished during the 30-day period covered by TCM. Most importantly, a practitioner will be able to bill for chronic care management (CPT® codes 99490, 99491, 99487, and 99489) and care plan oversight (HCPCS G0181 and G0182) furnished during the same time period as TCM.

Also, CMS is improving payment for TCM by increasing the work relative value units (RVUs) for the two TCM CPT codes. For CPT 99495, payment is increasing from \$166.50 to \$175.76. For CPT 99596, it will increase from \$234.97 to \$237.11. (Please note we use the non-facility national payment rate calculated with the 2020 conversion factor of \$36.09 throughout this article, unless noted otherwise.)

CCM – Chronic Care Management

For detailed information on CCM reimbursement rules, view PYA’s white paper, *Providing and Billing Medicare for Chronic Care Management*.

As with TCM, CMS notes that CCM is “increasing patient and practitioner satisfaction, saving costs and enabling solo practitioners to remain in independent practice.” Like TCM, however, CCM “continue[s] to be underutilized.”

To address this, CMS is creating an add-on code for non-complex CCM, HCPCS code G2058. Effective January 1, 2020, a practitioner can bill CPT 99490 for the first 20 minutes of clinical staff time spent performing CCM activities in a given calendar month and can bill G2058 for the second and third 20-minute increments.

Module 10 | Things to Know PMBi Study Guide

Payment for CPT 99490 is \$42.23, while each add-on code (up to two) pays \$37.89. Thus, total reimbursement for an hour or more of non-complex CCM services is \$118.01.

CMS is making one minor revision to the list of items typically included in the required comprehensive care plan, replacing “community/social services ordered, how the services of agencies and specialists unconnected to the practice will be directed/coordinated, identify the individuals responsible for each intervention” with this language: “interaction and coordination with outside resources and practitioners and providers.”

CMS is also revising the care planning element for complex CCM (CPT 99487 and 99489). CMS will now interpret the code descriptor “establishment or substantial revision of a comprehensive care plan” to mean that a comprehensive care plan is established, implemented, revised, or monitored.

PCM – Principal Care Management

Effective January 1, CMS will reimburse for PCM furnished to beneficiaries with a single chronic condition. The following table identifies the key differences between CCM and PCM services:

	Chronic Care Management	Principal Care Management
Base CPT/HCPCS Code	99490	G2065
Total RVU/Payment	1.17/\$42.22	1.10/\$39.70
Time Requirement (services furnished by clinical staff under general supervision)	20 minutes/month	30 minutes/month
Number of Chronic Conditions	2 or more	1
Billing Practitioner (most cases)	Primary care provider	Specialist
Scope of Service	Manage total patient care	Manage disease-specific Care
Likely Trigger	General need for care coordination, communication	Exacerbation of condition or hospitalization

Note: These summarizations are not strict service requirements, rather, a brief synopsis of intended use of the codes based on various readings of CMS regulatory guidance and other materials.

Concerned about paying for duplicative services, CMS includes two additional requirements for PCM:

(1) the practitioner billing for PCM must document in the patient’s record ongoing communication and care coordination between all practitioners furnishing care to the beneficiary, and (2) the practitioner cannot bill

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for interprofessional consultations or other care management services (excluding remote patient monitoring for the same beneficiary for the same time period as PCM).

As with CCM, CMS will reimburse for PCM services furnished directly by a physician or non-physician practitioner (as opposed to clinical staff under general supervision) under HCPCS code G2064. Payment will be \$78.68 for 30 minutes or more of care management services.

Finally, CMS declined to create an add-on code to reimburse for time spent beyond 30 minutes per month providing PCM. The agency noted it will monitor PCM utilization to determine whether such additional reimbursement is warranted.

RPM – Remote Patient Monitoring (Mainly what home health agencies are doing)

For detailed information on RPM reimbursement rules, view PYA's white paper, *Providing and Billing Medicare for Remote Patient Monitoring*.

Similar to non-complex CCM billed under CPT 99490, RPM billed under CPT 99457 requires 20 minutes of clinical staff time per calendar month reviewing and taking action based on data reported through RPM, including interactive communication with the patient or caregiver. CMS previously has required the billing practitioner to provide direct supervision (i.e., in-person) for clinical staff furnishing RPM services. Effective January 1, CMS will permit these services to be performed under general supervision.

Also, CMS has created an RPM add-on code, CPT 99458, similar to the non-complex CCM add-on code. Effective January 1, 2020, a practitioner can bill CPT 99457 for the first 20 minutes of clinical staff time spent performing RPM activities and CPT 99458 for the second and third 20-minute increments.

Payment for CPT 99457 is \$51.63, while each add-on code (up to 2) pays \$42.23. Thus, total reimbursement for an hour or more of RPM services is \$136.09. (Unlike non-complex CCM, CMS did not explicitly state only two units of CPT 99458 can be billed each calendar month. This limitation, however, is implicit in CMS' discussion regarding the RPM codes.)

CMS noted that “[s]everal commenters expressed concerns about the ambiguity of the code descriptors for the RPM codes.” The agency responded that it “appreciate[s] the many questions raised by commenters about the set of RPM codes and understand[s] the frustration commenters expressed with the current code descriptors. Therefore, given the numerous questions raised by commenters, [CMS] plan[s] to consider these and other questions related to RPM in future rulemaking.”

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Texas Rates



In- Home Telemonitoring Program (Medicaid Program)

Physician Reimbursement

New Billing Code (Professional only)	Expected Reimbursement Amount	Description
99421	\$ 15.52 (weekly)	Online digital evaluation and management service for and established patient for up to 7 days, cumulative time during the 7 days of 5-10 minutes
99422	\$31.04	11-20 minutes
99423	\$50.16	21 or more minutes

Additional modifiers for non-physician healthcare professionals

In-home telemonitoring enrollment requirements:

1. DM or HTN
2. 2 of 7 Risk Factors
3. FDA Class II medical devices
4. Electronically synced and transmitted data
5. 60 day episodes with pre-approval via institutional provider

Bridge Report: Coming Soon

REFERENCES: - [TMHP February 2020 Manual](#)

CC-RPM

NOTHING DUE FROM THE PATIENT

CCM \$8 DUE FROM THE PATIENT MONTHLY

HH buys the equipment for around \$130-\$140 to put in patient home - HH is monitoring it and has a contract with the doctor. The doctor bills "incident to" and they revenue share. Doctor has to pay the HH.

4 codes to be billed

99453. \$20 one time code for install of equipment

99454. \$64 for monthly monitoring. At least 16 days of readings

99457. \$52 for the first 20 minutes of oversight per month

99458. \$42. For each additional 20 minutes (up to 2 per month)

The software does everything for you and allows 1 person to be able to handle 300 patients.

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