



**Federal and State
Regulatory Update**

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2016 – A Year In Review

- Topics:
 - Opioids
 - Home Health Agencies
 - MACRA MIPS and Advanced APMs
 - Long-Term Care Facilities
 - Medicaid and CHIP Managed Care Final Rule
 - Human Subjects Research
 - CMS 60-Day Medicare Overpayment Rule
 - CMS Provider Directory Inaccuracy Final Rule

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Opioid Epidemic

- There is an opioid addiction epidemic nationwide.
- Health care providers wrote 259 million prescriptions for opioid pain medication in 2012. This is enough for every adult in the U.S. to have a bottle of pills.
- 7.3% increase per capita from 2007 to 2012.
- Among health care providers, there is a lack of consensus about how to use opioid pain medication.

From <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>

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Opioids

- The CDC's finalized Guidelines for Opioid Administration for Chronic Pain
 - New guideline provides recommendations for prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care.

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Opioids

- The CDC's finalized Guidelines for Opioid Administration for Chronic Pain
 - Guideline topics:
 1. When to begin or continue opioids for chronic pain
 2. Opioid selection, doses, duration of treatment, follow-up, and discontinuation; and
 3. Determining risk and harms of opioid use

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Opioids

- The CDC's finalized Guidelines for Opioid Administration for Chronic Pain
 - Guideline 1: Determining When to Initiate or Continue Opioids for Chronic Pain
 - Nonpharmacologic and nonopioid pharmacologic therapy are preferred.
 - If opioids are used, combine them with nonpharmacologic and nonopioid pharmacologic therapy as appropriate.

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Opioids

- The CDC's finalized Guidelines for Opioid Administration for Chronic Pain
 - Guideline 1: Determining When to Initiate or Continue Opioids for Chronic Pain
 - Before starting opioid therapy, clinicians should
 - Establish realistic treatment goals for pain and function with all patients;
 - Have a realistic "exit strategy" if benefits do not outweigh risks; and
 - Discuss risks and benefits, and patient/clinician responsibilities during treatment
 - Continue therapy only if there is clinically meaningful improvement in pain and function that outweighs safety risk.

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Opioids

- The CDC's finalized Guidelines for Opioid Administration for Chronic Pain
 - Guideline 2: Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation
 - When beginning opioid therapy, clinicians should prescribe lowest effective dosage of immediate-release opioids instead of extended-release/long-acting opioids.
 - Should prescribe no greater quantity than needed for the expected duration of pain.
 - Three days or fewer will usually be enough; > 7 days is rarely needed.
 - Avoid or "carefully justify" increasing dosage to ≥ 90 morphine milligram equivalents per day.

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Opioids

- The CDC's finalized Guidelines for Opioid Administration for Chronic Pain
 - Guideline 2: Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation
 - Carefully reassess evidence of individual risks and benefits when considering increase in dosage.
 - Clinicians should weigh benefits and harm with patients 1-4 weeks of either starting therapy or escalating dose.
 - Clinicians should evaluate benefits and harm with patients every 3 months or more.
 - If benefits do not outweigh harm, clinicians should optimize other therapy and work with patients to either taper or discontinue opioids.

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Opioids

- The CDC's finalized Guidelines for Opioid Administration for Chronic Pain
 - Guideline 3: Assessing Risk and Addressing Harms of Opioid Use
 - Clinicians should use the state prescription drug monitoring program data to review patient's history of controlled substance prescriptions, at the start of therapy and periodically throughout treatment.
 - Determine whether patient is receiving opioid dosages or dangerous combinations that put her at high risk for overdose.
 - Data should be reviewed at least every 3 months.
 - Consider offering naloxone when certain factors are present that increase risk for opioid overdose.
 - History of overdose
 - History of substance use disorder
 - Higher opioid dosages (>50 MME/day)
 - Concurrent benzodiazepine use

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Opioids

- The CDC's finalized Guidelines for Opioid Administration for Chronic Pain
 - Guideline 3: Assessing Risk and Addressing Harms of Opioid Use
 - Use urine drug testing before starting opioid therapy.
 - Consider urine drug testing annually to review for prescribed medications and other substances.
 - Avoid prescribing opioids and benzodiazepines concurrently.
 - For patients with opioid use disorder, offer or arrange evidence based treatment.
 - Usually medication-assisted treatment with buprenorphine or methadone combined with behavioral therapies.

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Medicare and Medicaid Home Health Care Beneficiary Protections

- Centers for Medicare & Medicaid Services (“CMS”) finalized new rules for Medicare and Medicaid Home Health beneficiary protections.
- They are designed to improve the quality of health care services for patients and strengthen patients’ rights.
- These Conditions of Participation are the minimum standards a home health agency must meet to participate in Medicare and Medicaid.

From: <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-01-09.html>

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Medicare and Medicaid Home Health Care Beneficiary Protections

- Final rule includes:
 - Condition of Participation enumerates rights of home health agency patients and the steps that must be taken to guarantee those rights.
 - An expanded patient assessment requirement about all aspects of patient well-being.
 - A requirement to assure that patients and caregivers have written information about upcoming visits, medication instructions, treatments administered, instructions for care that the patient and caregivers perform, and the name and contact information of a home health agency clinical manager.

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Medicare and Medicaid Home Health Care Beneficiary Protections

- Final Rule includes:
 - Integrated communication system that:
 - Ensures patient needs are identified and addressed,
 - Provides coordination of care among all disciplines, and
 - Promotes active communication between the home health agency and the patient’s physician(s).
 - Requirement for a data-driven, agency-wide quality assessment and performance improvement (QAPI) program to evaluate and improve agency care for all patients at all times.
 - A new infection prevention and control requirement.

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Medicare and Medicaid Home Health Care Beneficiary Protections

- Final rule includes:
 - A skilled professional services requirement designed to streamline appropriate patient care activities and supervision.
 - Patient care coordination requirement that gives a licensed clinician responsibility for all patient care.
 - Revisions to simplify the organizational structure of home health agencies.
 - Personnel qualifications for administrators and clinical managers.

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MACRA MIPS and Advanced APMs.

- Medicare Access and CHIP Reauthorization Act (“MACRA”).
- Merit-Based Incentive Payment System (“MIPS”).
- Advanced Alternative Payment Models (“Advanced APMs”).
- CMS developed a final rule to implement MACRA MIPS and Advanced APMs.
- Collectively, these programs are called Quality Payment Program (“QPP”).

From: <https://www.ama-assn.org/sites/default/files/media-browser/public/physicians/macra/macra-qpp-summary.pdf>

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MACRA MIPS and Advanced APMs

- CMS adopted many recommendations from AMA and made significant changes from the proposed rule:
 - Reduced reporting requirements from 9 quality measures to 6.
 - Made the transition period more realistic and flexible.
 - Increased the low-volume threshold to exempt more physicians from all performance reporting.
 - New threshold is \$30,000 Medicare revenue annually or ≤100 Part-B enrolled Medicare beneficiaries.
 - Eliminated the cost category by calculating 2017 composite performance scores.

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MACRA MIPS and Advanced APMs

Quality Payment Program Overview

- CMS finalized a transition year for the 2017 performance period.
 - For positive payment adjustment, physicians must report more than one patient for one quality measure, improvement activity, or required advancing care information (ACI) measures.
 - To avoid payment penalty in 2019, physicians must report for one patient on one quality measure, one improvement activity, or the required ACI measures in 2017.
 - Physicians will experience a -4% payment penalty in 2019 if they do not report any performance data.

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MACRA MIPS and Advanced APMs

MIPS

- Shortened the performance period.
 - Physicians who report for at least 90 continuous days in any of three categories to be included in the 2017 score will be eligible for positive payment adjustments.
- Increased the low-volume threshold to exempt more physicians from all performance reporting.
 - New threshold is \$30,000 Medicare revenue annually or ≤100 Part-B enrolled Medicare beneficiaries.
- Increased non-patient facing eligible clinicians encounter threshold.
 - CMS expanded the definition of a "non-patient facing physician" as someone who bills ≤100 patient-facing encounters during the determination period.
- Allowed for individual or group reporting.

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MACRA MIPS and Advanced APMs

Alternative Payment Models (APMs)

- Reduced the amount of losses defined as "more than nominal" in Advanced APMs.
 - An APM will qualify as an Advanced APM in 2019 and 2020 if the APM entity is either:
 - At risk of losing 8% of revenues when Medicare expenditures are higher than expected or
 - At risk of repaying CMS up to 3% of total Medicare expenditures, whichever is lower.
- To qualify as a Medicare Advanced APM, the APM only needs to meet the requirement for total risk, not marginal risk or minimum loss rate as previous version suggested.
- In 2017, 50% participants in Advanced APMs would need to use certified electronic health record technology (CEHRT).

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Long-Term Care Facilities

- CMS finalized improvements in care, safety, and consumer protections for long-term care facility residents:
 - This is the first major rewrite of the Conditions of Participation for LTC facilities since 1991.
 - Final rule includes additional protections required by the Affordable Care Act.

From <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-09-28.html>

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Long-Term Care Facilities

Changes include:

- Rights of residents are strengthened.
- Pre-dispute binding arbitration agreements are prohibited.
- Staff members must be properly trained to care for residents with dementia and to prevent elder abuse.
- Residents' care plans will take into consideration their goals of care and preferences.

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Long-Term Care Facilities

Changes also include:

- Dietitians and therapy providers are now permitted to write orders in their area of expertise if a physician delegates that responsibility and if state laws allow.
- LTC facility's infection prevention and control program must be updated to include an infection prevention and control officer and an antibiotic stewardship program. Programs must also include antibiotic use protocols and a system to monitor antibiotic use.

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Medicaid and CHIP Managed Care Final Rule

- This is the first major update to Medicaid and CHIP managed care regulations in over 10 years.
- Key provisions:
 - Align key rules with other health insurance coverage program rules;
 - Modernize how states purchase and deliver managed care for beneficiaries; and
 - Strengthen the consumer experience, including major consumer protections.

From <https://www.medicaid.gov/medicaid/managed-care/guidance/final-rule/index.html>
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Medicaid and CHIP Managed Care Final Rule

- Key provisions:
 - Reform states' delivery systems.
 - Support and enhance fiscal integrity and accountability.
 - Strengthen delivery of managed long term services and support.
 - Improve the quality of care for Medicaid beneficiaries.
 - Modernize other aspects of Medicaid and CHIP managed care.

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DHHS Human Subjects Research Final Rule

- Important elements include:
 - Consent forms must include a concise explanation of key information (purpose of research, risks and benefits, and alternative treatments) at the top of the form.
 - In most cases, a single institutional review board ("IRB") for multi-institutional studies is required.
 - Researchers may rely on broad consent for future research as an alternative to seeking IRB approval to waive the consent requirement.

From <https://www.hhs.gov/about/news/2017/01/18/final-rule-enhances-protections-research-participants-modernizes-oversight-system.html>
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DHHS Human Subjects Research Final Rule

- Important elements also include:
 - New exempt categories of research are established based on the level of risk posed to participants.
 - The requirement to conduct continuing review of ongoing research studies is removed in certain instances.
 - Consent forms for certain federally funded trials must be posted on a public website.

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Reporting and Returning Medicare Overpayments

- CMS released a final rule that is now in effect.
 - The rule applies to Medicare Part A and B providers and suppliers
 - (A separate final rule was published in 2014 that applies to Medicare Parts C and D.)
 - There is a 60-day deadline to report and return Medicare overpayments.
 - Counted from the later of:
 - The date an overpayment is identified or
 - The due date of any corresponding cost report.

From <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-02-11.html>
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Reporting and Returning Medicare Overpayments

- Other provisions:
 - Providers and suppliers must use appropriate methods to satisfy reporting and repayment obligations.
 - i.e. An applicable claims adjustment, credit balance, self-reported refund, or another appropriate method.
 - Look-back period is 6 years of the date the overpayment was received.

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Provider Directory Requirements

- CMS issued letters to issuers of qualified health plans (“QHPs”) and Medicare Advantage plans:
 - Health insurers must provide accurate doctor directories for policies that fall under Medicare Advantage and Healthcare.gov.
 - A QHP issuer must update directories at least monthly.
 - Directories must be publicly available on QHP’s websites in a machine-readable file and format.
 - HHS may impose CMPs against QHP and stand-alone dental plan (SADP) issuers of up to \$100/day per individual “adversely affected by the QHP or SADP issuer’s non-compliance.”

From
https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2016_Letter_to_Issuers_2_20_2015.pdf and
<https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/2015-02-20-15-01-01.pdf>.

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2017 – What’s Ahead?

- Affordable Care Act changes
 - “Repeal and Replace”?
- Changes to Medicare
 - “Vouchers”?

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Questions?

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