MEDICARE, MEDICAID AND MORE FOR HEALTH LAWYERS

2022 Seminar Material

M1148.22

New Jersey Institute for Continuing Legal Education

A Division of the State Bar Association
NJICLE.com

This page intentionally left blank

MEDICARE, MEDICAID AND MORE FOR HEALTH LAWYERS

Moderator/Speaker

Lisa D. Taylor, Esq.
Inglesino, Webster, Wyciskala & Taylor, LLC
(Parsippany)

Speakers

Joseph Milestone, Esq.
Rutgers University
(New Brunswick)

Eric Rubenstein, MSCJ, CFE
Advize Health
(Winter Park, FL)

M1148.22

Table of Contents

	Page
Medicare and Medicaid Basics Joseph Milestone, Esq.	1
Outline	1
The Medicare Program	3
History and Background	3
Medicare Structure	3
Medicare Terminology	8
Program Administration	9
Medicare Enrollment	10
Medicare Part A Coverage and Reimbursement	15
Medicare Part B Coverage and Reimbursement	17
Alternative Payment Models	25
Telemedicine	48
New(ish) Medicare Cards – Social Security Removal Initiative (SSNRI)	52
The Medicaid Program	53
Background	53
Eligibility	54
Managed Care	59
Physician Enrollment/Participation and Non-Billing Provider	60
Children's Health Insurance Program	62
Medicaid Services	62
Third Party Liability in the Medicaid Program	66
Evaluation and Management Services	67
Background	67
Office Visits – New Patients vs. Established Patients	69
Basic Principles of Medical Record Documentation	75
Consultations	76
E/M Service Documentation Provided by Students	77
Shared or Split Services	77
Glossary of Medicare/Medicaid Terminology and List of Abbreviations	81
Medicare and Medicaid Basics PowerPoint Presentation Joseph Milestone, Esq.	87
Anatomy of an OIG Investigation: Implications and Stop-Gap Measures for Compliance Professionals PowerPoint Presentation Eric Rubenstein	125
Medicare and Medicaid Special Issues PowerPoint Presentation Lisa D. Taylor, Esq.	149
About the Panelists…	159

This page intentionally left blank

Medicare and Medicaid Basics

Joseph Milestone, Esq.
Senior Associate General Counsel
Rutgers, The State University of New Jersey

Outline

The Medicare Program

I. History and Background
II. Medicare Structure
III. Medicare Terminology
IV. Program Administration
V. Medicare Enrollment
VI. Medicare Part A Coverage and Reimbursement
VII. Medicare Part B Coverage and Reimbursement
VIII. Alternative Payment Models
IX. Telemedicine
X. New(ish) Medicare Cards

The Medicaid Program

I. Background
II. Eligibility
III. Managed Care
IV. Physician Enrollment/Participation and Non-Billing Provider
V. Children's Health Insurance Program (CHIP)
VI. Medicaid Services
VII. Third Party Liability in the Medicaid Program

Evaluation and Management Services

I. Background
II. New Office Patients and Established Office Patients

III. Basic Principles of Medical Record Documentation
IV. Consultations
V. E/M Service Documentation Provided by Students
VI. Shared or Split Services

Glossary of Medicare/Medicaid Terminology and List of Abbreviations

The Medicare Program.

I. History and Background.

On July 30, 1965, the Compromise Social Security Amendments of 1965 (Pub.L. No. 89-87), adding Title XVIII (Medicare) and Title XIX (Medicaid) to the Social Security Act, were signed into law by President Lyndon B. Johnson.

Medicare now covers about 62.6 million people ages 65 and over and younger people with permanent disabilities. In 2020, Medicare benefit payments totaled $829.5 billion, up from $462 billion in 2006. In 2020, spending on Medicare accounted for 12% of the federal budget, down from 15% of the 2018 federal budget. Medicare plays a major role in our country's health care system, accounting for 20% of total national health spending in 2020, 30% of spending on retail sales of prescription drugs, 20.5% of spending on hospital care, and 23% of spending on physician services. For the most part, these numbers reflect a reduction due to Covid.

Over the 2019-2028 period, Medicare is projected to experience an annual growth rate of 7.6%, largely driven by enrollment growth, increased use of services and intensity of care, and rising health care prices. This is an increase of 2.5% when I last gave this presentation back in 2018.

II. Medicare Structure.

Medicare is organized into four separate programs: Part A (Hospital Insurance); Part B (Supplementary Medical Insurance); Part C (Medicare Advantage); and Part D (Prescription Drug Coverage). The term "Part" refers to divisions within Title XVIII of the Social Security Act. Each Part is financed differently and offers a distinct type of beneficiary coverage.

A. Medicare Part A.

Medicare Part A covers inpatient hospital and critical access hospital (CAH) care, post-hospital skilled nursing facility (SNF) care, some hospital outpatient costs, some home health services, and hospice care. Medicare Part A is financed through the federal Hospital Insurance (HI) Trust Fund, which is funded through payroll tax contributions from workers and employers. No premium payments are required for those automatically eligible for Part A. When you hear experts discuss the dangerously low levels in the Medicare Trust Fund, they are referring to Part A.

About 99% of Medicare beneficiaries do not have a Part A premium since they have at least 40 quarters of Medicare-covered employment. Enrollees age 65 and over who have fewer than 40 quarters of coverage and certain persons with disabilities pay a monthly

premium in order to voluntarily enroll in Medicare Part A. Individuals who had at least 30 quarters of coverage or who were married to someone with at least 30 quarters of coverage may buy into Part A at a reduced monthly premium rate, which is $274 in 2022. Uninsured aged and certain individuals with disabilities who have exhausted other entitlement and who have less than 30 quarters of coverage will pay the full premium, which is $499 a month.

Beneficiaries are responsible for cost-sharing requirements, including deductibles, coinsurance and copayments on most services. In 2022, beneficiaries will pay a $1,556 inpatient hospital deductible; this deductible is paid for each hospital stay within a benefit period. (A benefit period begins the day a patient is admitted as an inpatient in a hospital or SNF and ends when that patient hasn't received any inpatient hospital care (or skilled care in a SNF) for 60 days in a row.) There is no copayment for days 1-60. Daily copayments for hospital stays are $389 for days 61-90 and $778 for days 91-150 (called, "lifetime reserve days" = up to 60 days over your lifetime). Once the lifetime reserve days are exhausted, the beneficiary is responsible for all hospital charges. In a skilled nursing facility, there is no co-pay for the first 20 days of each benefit period, the co-pay is $194.50 per day for days 21-100 of each benefit period; then the patient is responsible for all costs after day 100 of the benefic period. Beneficiaries enrolled in Medicare Part C or a Medigap policy can avoid some or all of these deductibles and co-pays.

B. Medicare Part B.

Medicare Part B covers medical and other health services, including physicians' services, outpatient hospital department care, laboratory services, some home health care, physical and occupational therapy, durable medical equipment (DME) and supplies, diagnostic imaging, x-ray therapy and radiation therapy, medical supplies, ambulance services, rural health clinic services, home dialysis supplies and equipment, vaccines, screening mammography, clinical psychologists and clinical social workers.

Medicare Part B, also known as Supplementary Medical Insurance (SMI) is a voluntary program. Medicare Part B is financed through the SMI Trust Fund, which in turn is funded by individual premiums and general tax revenues. Premium payments for Part B enrollees are automatically deducted from the individual's Social Security checks.

Since 2007, Part B premiums have been based on modified gross income. The standard monthly premium for Medicare Part B enrollees is $170.10 for 2022. However, a statutory "hold harmless" provision applies to about 70% of Medicare beneficiaries. For these enrollees, any increase in Part B premiums must be lower than the increase in their Social Security benefits. In 2022, Social Security benefits increased by 5.9% due to a

cost-of-living adjustment. In prior years, the COLA was not as large; as a result, about 2% of all Part B enrollees who were subject to the hold harmless provision paid less than the full monthly premium. However, since 5.9% is the largest COLA since 1982, it is likely that the 2% number remain unchanged.

Those Part B enrollees who are not subject to the "hold harmless" provision will pay the full premium of $170.10 per month in 2022. Medicare Part B enrollees not subject to the "hold harmless" provision include beneficiaries who do not receive Social Security benefits, those who enroll in Part B for the first time in 2022, those who are directly billed for their Part B premium, those who are dually eligible for Medicaid and have their Medicare Part B premium paid by the state Medicaid agencies, and those who pay an income-related premium. These groups represent approximately 30% of total Part B beneficiaries.

Since 2007, beneficiaries with higher incomes have paid higher Medicare Part B monthly premiums. These income-related monthly adjustment amounts (IRMAA) affect roughly 7% of people with Medicare Part B. For individuals who report less than $91,000 yearly income, or couples who report less than $182,000 yearly income, the Part B premium is $170.10 per person per month, so those individuals pay no IRMAA. The monthly IRMAA of $68.00 per month kicks in for individuals reporting annual income above $91,000 up to $114,000 and couples reporting annual income above $182,000 up to $228,000. Monthly IRMAA payments increase in tiers for individuals and couples thereafter. Basically, IRMAA payments subsidize the Part B premiums of Medicare enrollees eligible for the hold harmless provision.

In 2022, the Medicare Part B deductible is $233.00 per year (this could be paid by a Medicare Advantage or a Medigap plan). After the deductible, Part B generally pays 80% of Medicare approved charges and the beneficiary pays 20%. Again, beneficiaries can reduce or eliminate these copay obligations through enrollment in a Medicare Advantage plan or a Medigap supplemental insurance plan.

C. Medicare Advantage (Medicare Part C).

Formerly known as Medicare+Choice, the "Medicare Advantage" or "MA" program offers Medicare beneficiaries a range of managed care coverage choices. Beneficiaries with traditional Part A and Part B coverage may continue to receive such traditional fee-for-service coverage or may elect MA coverage through a Medicare-approved private managed care organization for a monthly premium. The MA coverage replaces the "original" Part A and Part B coverage. In 2021, about 42% of Medicare beneficiaries were enrolled in MA plans. Medicare beneficiaries who enroll in Medicare

Advantage continue to pay their Part B premium and also pay a second premium for Medicare Advantage.

At a minimum, every MA plan must provide beneficiaries with all of the items and services offered by Parts A and B, with limited exceptions. Most offer additional benefits to encourage enrollment, such as prescription drugs, vision, dental, hearing, and wellness programs. Payments to MA organizations are financed through the HI and SMI Trust Funds and supplemented by premiums paid by beneficiaries. The amount of the premium depends on the richness of the plan. Based on CMS estimates, the Medicare Advantage average monthly premium for 2022 is approximately $19.00. Some Medicare Advantage plans cost $0 per month and others cost well over $100.

Since 2011, all MA plans have been required to limit beneficiaries' out-of-pocket spending (called, MOOP) for services covered under Medicare Parts A and B to no more than $7,550 (in-network) or $11,300 (in-network and out-of-network combined).

There are four different major types of MA plans:

1. Medicare Managed Care Plans (HMOs). Members must see doctors in the plan's network. In most cases, a primary care doctor coordinates health care.

2. Medicare Preferred Provider Organization Plans (PPOs). Members may see any doctor, but it costs less to see doctors within the plan's provider network.

3. Medicare Fee-for-Service Plans. Members may visit any Medicare-approved doctor or hospital if that care provider agrees to the plan's terms and conditions of payment before treatment. The plan decides how much it will pay the providers and the cost sharing for the beneficiary.

4. Medicare Special Needs Plans. These plans provide health care coverage for special needs, such as chronic illness, beneficiaries in institutions and beneficiaries with Medicaid.

Less common Medicare Advantage plans include:

5. Medicare Medical Savings Account Plans. These plans have two parts: a Medicare Advantage Plan with a high deductible and a Medical Savings Account into which Medicare deposits money that people can use to pay

health care costs.

6. HMO Point of Service Plans. These are HMO plans that permit beneficiaries to obtain some services out-of-network at a higher cost.

D. Medicare Part D.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 established a voluntary outpatient prescription drug benefit for Part A eligible or Part B enrolled beneficiaries that became operational in 2006. Part D covered drugs include Medicaid-covered prescription drugs, biologicals, and vaccines. The goal of the program is to provide beneficiaries access to prescription drugs at lower cost due to CMS negotiated prices. The Part D benefit, which is provided through prescription drug plans (PDPs) and MA plans that offer drug coverage, is financed through a separate account in the SMI Trust Fund and is administered by CMS.

Part D enrollees pay a premium which varies by plan. The average premium for a Medicare prescription drug plan in 2022 is $43.00 per month for a basic plan. The average monthly premiums for the 16 national PDPs range from $7.00 to $99.00 in 2022.

In addition, Part D enrollees pay a Part D income-related monthly adjustment amount (Part D-IRMAA). This extra amount is paid directly to Medicare, not to the enrollee's plan, and is in addition to the Part D premium. Therefore, a Part D enrollee pays two charges each month – an IRMAA fee to CMS and a premium to the Part D plan. For individuals who report less than $91,000 yearly income, or couples who report less than $182,000 yearly income, the Part D IRMMA fee is $0 per person per month. The IRMAA fee increases to $77.90 per person per month for individuals reporting in excess of $500,000 yearly income and couples in excess of $750,000/year.

In addition to basic plans, Part D permits PDPs to offer "enhanced" plans that offer more generous prescription drug coverage than Part D basic benefit designs. These enhanced plans can reduce cost sharing beyond basic Part D plan types, such as fixed dollar copays instead of setting out-of-pocket costs to be a percentage of a drug's price (i.e., coinsurance). In exchange for these additional benefits, enhanced plans have slightly higher premiums, which are paid for by beneficiaries or through other means, such as a Medicare Advantage plan. In 2022, average monthly premiums for Part D enhanced plans are $51.00.

Part D has the infamous "donut hole," which is a gap in coverage. Under the Defined Standard Benefit, each beneficiary pays an annual deductible (which cannot exceed $480

in 2022); some Part D plans don't have a deductible. After the deductible is met, beneficiaries pay 25% of covered costs up to the Initial Coverage Limit. In 2022, the Initial Coverage Limit is $4,430. After costs for covered drugs in a year reach the Initial Coverage Limit – this includes both the amount paid by insurance and the amount paid by the beneficiary – then beneficiaries are responsible for 25% of the cost of covered brand-name drugs and 25% of the price of generic prescription drugs. When the total out-of-pocket costs for the beneficiary reach $7,050, the hole closes (this is called "catastrophic coverage"); at that point, the beneficiary is responsible for only about 5% of his/her prescription drug cost for the rest of the year.

E. Supplemental Policies (Medigap).

Beneficiaries have the option of purchasing supplemental health insurance coverage from private commercial insurers. Known as "Medigap" or Medicare SELECT, these policies typically offer a range of coverage options for Medicare excluded services and help defray the cost of coinsurance and deductibles for Medicare beneficiaries. Medigap policies are available only to beneficiaries who are covered under "original" (Part A and Part B) Medicare.

Medigap plans are not formally a part of Medicare, but their benefits are subject to regulation. There are ten (10) standard Medigap plans, known as Plans A through D; F; G; and K through N. All plans with the same letter offer the same benefits. Here, too, premiums vary with the richness of the plan.

F. The Medicare Secondary Payor Rule.

Medicare does not pay for services for which Medicare is not the "primary" payor. Under such circumstances, Medicare's liability for payment is "secondary" to that of other health insurance plan(s). For example, a Medicare beneficiary was in an accident where no-fault or liability insurance is involved. The no-fault or liability insurance pays primary for care necessitated by the accident and Medicare pays secondary. Note that Medicare may be entitled to recovery of the amounts that it has paid if there is a settlement.

III. Medicare Terminology.

A. Beneficiary. *"Beneficiary"* is the Medicare term used to describe an individual enrolled in the Medicare program. With private payors outside the world of Medicare, these individuals are frequently referred to as *"enrollees."* Beneficiary also refers to an individual enrolled in the Medicaid program; they were previously called *"recipients."*

B. Provider vs. Supplier. The terms *"provider"* and *"supplier"* have distinct and express meanings in the world of Medicare regulations and reimbursement. While the terms are specifically Medicare defined terms, you may run into their usage in the private payor world as well. However, these terms may or may not carry the same meaning with private payors.

Specifically, a "provider" is defined to include hospitals, critical access hospitals (CAHs), skilled nursing facilities (SNFs), comprehensive outpatient rehabilitation facilities (CORFs), home health agencies (HHAs), hospice providers, rehabilitation agencies, public health agencies, certified clinics furnishing outpatient therapy services, and community mental health centers furnishing partial hospitalization services.

By contrast, the term "supplier" includes physicians; suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS suppliers); ambulatory surgery centers (ASCs); independent diagnostic testing facilities (IDTFs); ambulance services; physician assistants; and any entity other than a provider.

C. Assignment vs. Reassignment. "Assignment" and "reassignment" are two terms describing who receives payment for items, services, or supplies furnished to beneficiaries. "Assignment" relates to a patient assigning his or her right to medical benefits (e.g., payment from Medicare for incurring the expense of a physician visit) to providers and suppliers. "Reassignment" permits providers/suppliers to redirect payment to another person or entity (e.g., a physician's employer).

D. "Accepting Assignment". When a physician/supplier "accepts assignment" of a beneficiary's claim (that is, furnishes services on an assignment-related basis), the physician/supplier agrees not to charge the beneficiary more than the applicable deductible and coinsurance amounts based on the approved charge amount for the services and to accept those payments and the applicable Medicare payment as payment in full for the services.

IV. Program Administration.

A. General. Parts A, B and D of the Medicare program are administered by the federal government through the Department of Health and Human Services (HHS). HHS has overall responsibility for administration of the Medicare program and development of regulations implementing the Social Security Act. The Centers for Medicare and Medicaid Services (CMS) has day-to-day responsibility for administering the Medicare program. (CMS was formerly known as the Health Care Financing Administration (HCFA); that name was changed on June 14, 2001.)

B. Medicare Contractors. Provider/supplier enrollment and claims payment/appeals are carried out by private insurance companies under contract with CMS, including Medicare Administrative Contractors (MACs) and Part D prescription drug plans (PDPs). Prior to the development of MACs, administration of Parts A and B of the Medicare program were carried out by Fiscal Intermediaries (FIs), Medicare Carriers, the National Supplier Clearinghouse (NSC), and Durable Medical Equipment Regional Carriers (DMERCs).

- New Jersey is in MAC Jurisdiction L. The MAC for New Jersey is Novitas Solutions, Inc. (MAC Jurisdiction L includes Delaware, District of Columbia, Maryland, New Jersey and Pennsylvania.)

- New Jersey is in DME Jurisdiction A. The DMERC for New Jersey is Noridian Healthcare Solutions, LLC. (DME Jurisdiction A includes Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island and Vermont.)

V. Medicare Enrollment. Physicians, non-physician practitioners, (NPPs) and other health care suppliers must enroll in the Medicare program in order to be eligible to receive Medicare payment for covered services provided to Medicare beneficiaries.

A. Enrollment Process. Enrollment is a two-step process. Providers/suppliers must first obtain a National Provider Identifier; then they need to complete an online Medicare enrollment application.

1. National Provider Identifier (NPI). The NPI is the standard unique health identifier for health care providers and suppliers and is assigned by the National Plan and Provider Enumeration System (NPPES). This is also an entirely online service. The NPI number is a universal provider identifier and was designed to replace numbers issued by Medicare, Medicaid and every commercial health plan. Previously, Medicare had issued Unique Provider Identification Numbers (UPINs). The NPI number must be included on every health care claim form submitted to Medicare, Medicaid or commercial health plans. It is also possible to look up a provider's NPI number on the NPPES.

An NPI number is specifically linked to an entity's tax identification number (TIN).

2. Provider Enrollment, Chain and Ownership System (PECOS). This is an internet-based system through which providers and suppliers can: (a) submit

Medicare enrollment applications; (b) update enrollment information; and (c) complete the re-validation process. The entire form and all exhibits (including signatures) can be submitted electronically.

Applications vary depending on the nature of the provider/supplier:

CMS-855I	Medicare Enrollment Application (Physicians and Non-Physician Practitioners)
CMS-855B	Medicare Enrollment Application (Clinics/Group Practices and Certain Other Suppliers)
CMS-855A	Medicare Enrollment Application (Institutional Providers)
CMS-855R	Medicare Enrollment Application (Reassignment of Medicare Benefits)
CMS-588	Electronic Funds Transfer (EFT) Authorization Agreement

There is an application fee of $631 (CY2022) for providers and suppliers who submit forms 855A or 855B, but physicians and non-physician practitioner organizations are exempt. Hospitals, skilled nursing facilities, ambulatory surgery centers, durable medical equipment supplies, independent diagnostic testing facilities, independent clinical labs and other entities are subject to the application fee, while individual physicians, group practices, and non-physician practitioners (such as advanced practice nurses or certified physician assistants) are exempt from the application fee.

B. Participating Physician and Supplier Program. Participating physicians agree to accept Medicare's allowed charge as payment in full for all services provided to Medicare beneficiaries (plus applicable deductible and copayment amounts). The Medicare participating physician/supplier program offers incentives for becoming a participating physician or supplier. The main incentive is payment at a higher reimbursement rate under the fee schedule; nonparticipating physicians are paid at only 95% of the fee schedule. The Participation Agreement is a CMS-460 form.

Many practitioners, providers, and suppliers must accept assignment. Included are ASCs, CNMs, CRNAs, CSWs, NPs, PAs, Registered Dieticians, Anesthesiology Assistants, ESRD Suppliers, CORFs, Clinical Diagnostic Laboratories and Ambulances. Also, payment for any drug or biological covered under Medicare Part B may be made on an

assignment-related basis only.

C. Non-participating Physicians. Non-participating physicians are physicians who are enrolled in the Medicare program but can make assignment decisions on a case-by-case basis and may bill patients for more than the Medicare allowance for unassigned claims. Non-participating physicians are allowed to charge up to 115% of the Medicare-approved non-participation amount, which equals a maximum allowable charge of 109.25% of the participating physician rate.

How it works:

- The participating fee schedule for 90801 (Psychiatric Diagnostic Interview Examination) is $183.88
- The nonpar fee schedule for 90801 is $174.69 (or 95% of $183.88)
- Medicare will reimburse the participating provider at 80% of $183.88, or $147.10 and the patient is responsible for paying the remaining $34.78
- Medicare will reimburse the patient of a nonpar provider at 80% of $174.69 (equal to $139.75). The provider may bill his/her patient the limiting fee of $200.89 (which is 15% above $174.69) for the 90801 ($200.89-139.75=$61.14) which means the patient will wind up paying $61.14 out of pocket after the patient has been reimbursed by Medicare). The provider ends up a little over 9% ahead.

As a nonpar provider, the provider can decide to accept assignment (just as if they were a participating provider) on a claim-by-claim basis. On claims for which the provider decides to accept assignment, they will be reimbursed directly by Medicare, but will receive 5% less for them than they would as a participating provider. When a provider accepts assignment, they cannot bill the patient the limiting charge (the 15% above the nonpar amount) - the provider can only bill the limiting charge on claims for which they do not accept assignment. When a provider accepts assignment, they can only bill the patient for the co-pay.

The major disadvantage to being a nonpar Medicare provider is that if the provider wishes to take advantage of the 115% limiting charge by not accepting assignment, they must collect the entire fee from the patient, who will then be reimbursed by Medicare for a smaller percentage of the fee than he would otherwise receive. Medicare reimburses the patient for 80% of the nonpar fee before the limiting charge is added and the patient has to pay the extra amount out of pocket. When a physician chooses to accept assignment as a nonpar provider, because the physician doesn't want the difficulty of collecting the entire payment from the patient, then that physician ends up receiving less money than he/she would as a participating provider.

- Medicare requires all suppliers and providers enrolled in the Medicare program to submit claims for Medicare beneficiaries whether or not the supplier or provider participates.

- Part A providers (hospitals, skilled nursing facilities, etc.) must participate.

D. Private Contracting - Concierge Medicine. Medicare permits the use of "private contracts" between physicians, certain practitioners, and Medicare beneficiaries wherein the parties agree that no claims for reimbursement will be submitted to Medicare. Physicians and practitioners entering into such contracts must file an affidavit with HHS affirming that, for two years from the date of the affidavit, they will not submit any claims to Medicare for items or services provided for any Medicare beneficiary, nor receive payment from Medicare, either directly or indirectly, for items or services provided to any beneficiary. The beneficiary must acknowledge in writing their unlimited personal liability for the cost of medical care rendered under the contract.

- The Medicare Administrative Contractor for New Jersey, Novitas Solutions, has a sample affidavit on its website.

E. Loss of Medicare Billing Privileges. In the 2020 Physician Fee Schedule (84 Fed. Reg. 62568, 62926-62932 (Nov. 15, 2019)), CMS introduced sweeping changes that permit the denial of a Medicare enrollment application or a billing privilege revocation for professionals eligible to individually reenroll. These changes were buried in one of the 996 pages of the 2020 Physician Fee Schedule, included among the new requirements for opioid treatment programs. In taking this action, CMS has introduced some of the most significant and substantial changes to the rules for obtaining and maintaining Medicare enrollment since the rules were first established in 2006. These new regulations apply to physicians and other eligible professionals, which includes advanced practice nurses, therapists, and physician assistants.

Under its expanded authority at 42 CFR 424.530(a)(15) and 42 CFR 424.535(a)(22), Medicare now has the authority to deny enrollment or revoke current Medicare billing privileges for those physicians and eligible professionals who have ever been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible profession conduct that led to patient harm.

The comments to the final rule state:

b. Patient Harm

"As referenced previously, and due to the importance of ensuring patient safety in all provider and supplier settings (not merely those involving opioid treatment programs), we also proposed to add § 424.535(a)(22) as a new revocation reason; this would be coupled with a concomitant new denial reason in § 424.530(a)(15). These two paragraphs would permit us to revoke or deny, as applicable, a physician's or other eligible professional's (as that term is defined in section 1848(k)(3)(B) of the [Social Security] Act) enrollment if he or she has been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm. In determining whether a revocation or denial on this ground is appropriate, CMS would consider the following factors:"

- The nature of the patient harm.
- The nature of the physician's or other eligible professional's conduct.
- The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or other eligible professional by a state oversight board, IRO, federal or state health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. Such actions include, but are not limited to in scope or degree:
    - License restriction (s) pertaining to certain procedures or practices.
    - Required compliance appearances before state oversight board members.
    - License restriction(s) regarding the ability to treat certain types of patients (for example, cannot be alone with members of a different gender after a sexual offense charge).
    - Administrative/monetary penalties, or
    - Formal reprimand(s).
- If applicable, the nature of the IRO determination(s).
- The number of patients impacted by the physician's or other eligible professional's conduct and the degree of harm thereto or impact upon.

The following factors were considered in the proposed rule, but rejected in the final rule:

- Required participation in rehabilitation or mental/behavioral health programs.
- Required abstinence from drugs or alcohol and random drug testing.

"As noted in the proposed rule and in previous rulemaking efforts, we remain concerned about instances of physician or other eligible professional misconduct, and we believe our authority under sections 1102, 1866(j)(1)(A), and 1871 of the Act to take action to stem such behavior should be expanded to include the scenarios identified in § 424.530(a)(15) and § 424.535(a)(22). State oversight boards, such as medical boards and other administrative bodies, have found certain physicians and other eligible professionals to have engaged in professional misconduct and/or negligent or abusive behavior involving patient harm. In addition, IRO determinations have offered valuable, independent analyses and findings of provider misconduct that we should have the opportunity to use to promote the best interests of Medicare beneficiaries. We outlined our belief that our proposed revocation and denial authorities would improve overall patient care by preventing certain problematic physicians and other eligible professionals from treating Medicare patients."

Note that a Medicare revocation leads to a mandated cross-termination of participation in Medicaid and other federal payor programs.

VI. Medicare Part A Coverage and Reimbursement.

A. Prospective Payment System. Prospective payment systems (PPS) figure prominently in Part A reimbursement. Generally, a prospective payment system is a method of reimbursement in which Medicare payment is made based on a predetermined, fixed amount. The payment amount for a particular service is derived based on the classification system of that service (for example, diagnosis-related groups (DRGs) for inpatient hospital services or the patient driven payment model (PDPM) for skilled nursing facilities) and Ambulatory Payment Groups (APCs) for hospital outpatient departments. Hospital PPS was first implemented in 1983 and SNF PPS was first implemented in 2019.

B. Hospital Services. Inpatient hospital coverage includes the cost of semi-private rooms, meals, general nursing services, operating and recovery room, intensive care, inpatient prescription drugs, laboratory tests, x-rays, psychiatric hospital, inpatient rehabilitation and long term care hospitalization when medically necessary, as well as other medically necessary services and supplies provided in the hospital.

The majority of hospitals are paid according to inpatient hospital PPS (IPPS), which represents the average cost, nationwide, of treating a Medicare beneficiary according to his or her medical condition. IPPS hospitals are paid a predetermined flat rate for inpatient care that is based on the patient's diagnosis at discharge.

Hospital Outpatient Services are reimbursed under Part A pursuant to a prospective payment system called HOPPS - hospital outpatient prospective payment system.

Note that if you receive care from a physician in a hospital as an inpatient or an outpatient, you will receive two separate bills - one for the facility (billed to Part A) and one for the physician service (billed to Part B) and be subject to separate deductibles and co-pays for both bills. Facility fees are often charged by clinics that are owned by hospitals.

C. Skilled Nursing Facility Services. Extended care services in a skilled nursing facility (SNF) are similar to those for inpatient hospital care, but also include certain rehabilitation services and appliances. In a SNF, Medicare will pay for a semi-private room, meals, skilled nursing services, PT, OT, speech-language pathology services, medical social services, medications, medical supplies and equipment used in the facility, dietary counseling, and ambulance transportation to the nearest supplier of medically-necessary services that are not available at the SNF.

SNFs are paid a per diem rate using a resident classification system called the "Patient Driven Payment Model" (PDPM) which was introduced in 2019. Previously, CMS used "Resource Utilization Groups" or RUGs.

The first 20 days are fully covered by Medicare. Patients pay a daily coinsurance for days 21 – 100. That daily rate is $194.50 in 2022. There is no Medicare coverage beyond 100 days.

D. Home Health Care Services. Medicare provides coverage for certain "part-time" or "intermittent" medical, nursing and therapy services furnished to individuals in their homes by home health agencies (HHAs). In order to qualify for home health care, a Medicare beneficiary must: (i) be confined to the home; (ii) under the care of a physician: (iii) receiving services under a plan of care established and periodically reviewed by a physician; and, (iv) be in need of skilled nursing care on an intermittent basis (no more than 8 hours/day and no more than 28 hours/week), or physical therapy or speech-language pathology, or have a continuing need for occupational therapy.

HHAs are paid for each sixty-day episode of care using a prospective payment system

based on the "Home Health Resource Group" or HHRG system, which classifies HHA patients into one of 80 case-mix groups.

The first 100 days of HHA services are covered under Part A and cost beneficiaries $0. After those 100 days, services provided by HHAs are covered under Part B.

E. Hospice Services. Hospice care is a benefit under Part A that is provided to individuals who make an affirmative election to receive this benefit. To be eligible to elect for hospice care, an individual must be certified as "terminally ill" - i.e., the medical prognosis is that the individual's life expectancy is six months or less if the illness runs its normal course. Such care includes pain relief, supportive medical and social services, physical therapy, nursing services, symptom management, spiritual counseling and services from a hospice-employed physician, nurse practitioner or other physicians chosen by the patient.

Hospice care is reimbursed using a prospective payment system based on payment rates for specific categories of hospice care (e.g., routine home care, continuous home care, inpatient day respite care, and general inpatient day care) that are subject to a cost cap and an inflation update. Once a patient is certified as terminally ill, Medicare will pay for two 90-day periods followed by an unlimited number of 60-day periods.

After the second 90-day period, the recertification associated with a hospice patient's third benefit period and every subsequent recertification, must include documentation that a hospice physician or hospice nurse practitioner had a face-to-face (FTF) encounter with the patient. The FTF encounter must document the clinical findings supporting a life expectancy of 6 months or less.

VII. Medicare Part B Coverage and Reimbursement.

A. Medical and Other Health Services. Medicare Part B (the Supplementary Medical Insurance (SMI) program), covers medical and other health services, such as:

- Physician services
- Non-physician services (e.g., CRNA, physician's assistant, clinical social workers, nurse midwives, etc.)
- Supplies "incident to" physician services (e.g., drugs – but not self-administered drugs)
- Non-physician services "incident to" physicians' services.
- Outpatient services (including outpatient surgical services)
- Diagnostic services furnished to outpatients by or under arrangements

made by a hospital or CAH
- Diagnostic laboratory, x-ray or other diagnostic tests
- Medical supplies, appliances, and devices
- Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS)
- Ambulance services
- Outpatient physical therapy and speech pathology services
- Pneumococcal vaccinations, hepatitis B vaccine, blood clotting factors for hemophilia patients

There are two types of diagnostic tests: diagnostic laboratory tests and diagnostic non-laboratory tests. Diagnostic laboratory tests, also called clinical diagnostic laboratory tests, include certain blood tests, urinalysis, and tests on tissue specimens. Diagnostic non-laboratory tests include CT scans, MRIs, EKGs, X-rays and PET scans. While beneficiaries generally pay nothing for Medicare-covered diagnostic laboratory tests, beneficiaries do pay a deductible and copayment for diagnostic non-laboratory tests.

B. Reasonable and Necessary. Medicare may only pay for items and services that are "reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member." Medical necessity is both a coverage determination and a utilization determination, both of which are set forth in local and national coverage determinations. "Coverage" means that Medicare will pay for it, while "utilization" dictates how many units and how often Medicare will pay for it.

1. "National coverage determinations" or "NCDs" are determinations made by CMS with respect to whether or not a particular item or service is covered nationally by Medicare, but does not include a determination of what code, if any, is assigned to a particular item or service.

2. "Local medical review policies" (LMRPs) or "local coverage determinations" (LCDs) are contractor-specific policies that offer coverage and coding guidance for providers, physicians and suppliers in the MAC's specific geographic area.

C. Physicians' Services. Part B covers the professional services performed by a physician for a patient, including diagnosis, therapy, surgery, consultation and care plan oversight. The services must be personally performed by the physician or performed by others under the "incident to" provisions.

D. "Incident to" Services. "Incident to" refers to a Medicare billing mechanism,

allowing services furnished in an ambulatory setting to be provided by auxiliary personnel and billed under the provider's national provider identification (NPI) number. "Incident to" the provider's professional services means that the services or supplies are furnished as an integral, although incidental, part of the provider's professional services in the course of diagnosis or treatment of an injury or illness. The subordinate providers can include physicians, nurse practitioners, clinical nurse specialists, certified nurse midwives, physician assistants, clinical psychologists, clinical social workers and physical and occupational therapists. The services provided must be delivered under the provider's direct supervision; the provider must be in the area where care is delivered and be immediately available to provide assistance and supervision. The provider must initiate a course of treatment, and the service provided by the auxiliary staff is follow up care (that is, assisting in providing the plan of care).

> *Example 1.* A Medicare patient has been previously treated by the physician and diagnosed with hypertension. On a subsequent visit to the physician's office a PA saw the patient and evaluated the patient's hypertension within the plan of care established by the physician on the initial visit. The physician or another physician within the group was on-site, within the suite of offices at the time the PA saw and treated the patient, but at no time did a physician actually see the patient. The PA may bill the office visit, "incident to," under the physician's NPI number, with full reimbursement.
>
> *Example 2.* The physician asks that an established patient with ongoing high blood pressure return to the office in one week for blood pressure check. The physician documents that plan in the record. The patient returns as instructed, the RN takes the B/P and documents it in the chart. This is billed with CPT code 99211 using the physician's provider number; at no time did the physician actually see the patient.
>
> *Example 3.* The physician has been treating a patient for a chronic condition and asks the patient to return in one month for follow up. The patient is scheduled with the NPP. At the time of the visit, the physician is in the office suite. The NPP sees the patient and bills "incident to" under the physician's provider number; at no time did the physician actually see the patient.

E. Physician Supervision of Physician Assistants. The final 2020 Physician Fee Schedule rule issued by CMS changed Medicare's supervision requirements for PAs by largely deferring to state law on how PAs practice with physicians and other members of the healthcare team. This change took effect on January 1, 2020.

- CMS replaced the current Medicare requirement for the general physician supervision of physician assistants (PAs), including the immediate availability of the supervising physician to the PA for consultation, with medical direction and appropriate supervision as provided by state law.

- CMS streamlined documentation requirements for such physician supervision by allowing the physician, PA, or advanced practice registered nurse who furnishes and bills for his or her professional services to review and verify - rather than fully re-document - information included in the medical record by physicians, residents, nurses, medical, PA, and advanced practice registered nurse students, or other members of the medical team.

- Note that PAs, who previously were not eligible to receive direct payments from Medicare can now, effective January 1, 2022, submit claims directly to Medicare; previously, Medicare payments for PA services could only be remitted to the PA's employer.

F. Technical vs. Professional Components.

Certain procedures are a combination of a "physician component" and a "technical component." This is most frequently seen in diagnostic tests, such as x-ray or other imaging services.

The "professional component" represents the physician or other health care professional work portion (physician work/practice overhead/malpractice expense) of the procedure. The professional component is the physician or other health care professional supervision and interpretation of a procedure that: (i) is personally furnished to an individual patient by the physician or via "incident to" services; (ii) results in a written narrative report to be included in the patient's medical record; and (iii) directly contributes to the patient's diagnosis and/or treatment. In appropriate circumstances, it is identified by appending modifier "26" to the designated procedure code or by reporting a standalone code that describes the professional component only of a selected diagnostic test.

The "technical component "is the performance (technician/equipment/facility) of the procedure. In appropriate circumstances, it is identified by appending modifier "TC" to the designated procedure code or by reporting a standalone code that describes the technical component only of a selected diagnostic test.

A "global service" includes both professional and technical components. When a physician or other health care professional bills a global service, he or she is submitting

for both the professional and technical components of that code. Submission of a global service asserts that the same individual physician or other health care professional provided the supervision, interpretation and report of the professional services as well as the technician, equipment, and the facility needed to perform the procedure.

Note that the Medicare payment for reviewing results of diagnostic laboratory tests, phoning results to patients, filing such results, etc., are already included in the evaluation and management (E & M) services that were billed at the time that the physician prescribed the laboratory test - a physician is not allowed to bill a separate interpretation fee.

G. Place of Service. Don't confuse modifier number with the Place of Service Code. Every Medicare claim must identify the Place of Service; that is the location where the physician or non-physician practitioner rendered the service. In general, physicians and NPPs treat patients at an Office location; that this POS 11. Other popular POS codes are:

POS Code	Description
10	Telehealth Provided in Patient's Home
11	Office
12	Home
13	Assisted Living Facility
17	Walk-in Retail Health Clinic
20	Urgent Care Facility
21	Inpatient Hospital
22	On Campus-Hospital Outpatient
24	Ambulatory Surgical Center
31	Skilled Nursing Facility
34	Hospice

H. Anti-Markup Rule for Purchased Diagnostic Tests.

If a physician or other supplier bills for the technical component (TC) or professional component (26) of a diagnostic test that was ordered by the physician or other supplier (or ordered by a party related to such physician or other supplier through common ownership or control) and the diagnostic test is performed by a physician who does not share a practice with the billing physician or other supplier, the payment to the billing physician or other supplier for the TC or 26 of the diagnostic test may not exceed the lowest of the following amounts:

1. The performing supplier's net charges to the billing physician or supplier
2. The billing physician's or supplier's actual charge

3. The fee schedule amount that would apply if the performing supplier billed directly

This is called the "anti-markup" rule and it prevents a billing physician or other billing supplier from making a profit on a purchased diagnostic test.

I. Physician Payment under the Resource-Based Relative Value Scale (RBRVS)/ Medicare Physician Fee Schedule.

Medicare uses a physician fee schedule to determine payments for each of the over 10,000 services and procedures covered under its Physician Fee Schedule (PFS), and which are assigned current procedural terminology (CPT) code numbers. The fee for each service depends on its relative value units (RVUs), which rank on a common scale -- the Resource-Based Relative Value Scale (RBRVS) -- the resources used to provide each service. These resources include the physician's work, the expenses of the physician's practice, and professional liability insurance. To determine the Medicare fee, a service's RVUs are multiplied by a dollar conversion factor.

1. The Work RVU (wRVU) consists of the relative number of units involved in the work performed by the physician or provider. The wRVU is related to the direct expenses associated with what the physician receives for payment in salary and direct benefits and accounts for the time, technical skill and effort, mental effort and judgment and stress to provide the service.

2. The Practice Expense RVU (peRVU) represents the cost to operate the medical practice and is related to the general overhead expenses of the practice; it accounts for the non-physician clinical and nonclinical labor of the practice, as well as expenses for building space, equipment and office supplies. There are two types of peRVUs: facility (hospital) and non-facility (office). The non-facility rate is usually higher than the facility rate since it includes overhead expenses. This difference is sometimes referred to as the "Site of Service" differential. Not all CPT codes have a Site of Service differential. This differential is generally used by government payers. Further, the Site of Service differential does not apply to certain medical specialties (e.g., radiology), and in certain other non-office settings (e.g., hospital outpatient departments).

3. The Malpractice RVU (mRVU) estimates the relative risk of each CPT code. This is related to the cost of malpractice insurance for the physician and the practice.

The relative values are adjusted by geographic practice cost indices (GPCI) for each locality and the sum of the adjusted relative values for a service is multiplied by a national dollar conversion factor to determine the fee schedule amount.

For example, the Physician Work GPCI for Northern New Jersey in 2022 is 1.049 and the Rest of New Jersey is 1.037. In contrast, Manhattan is 1.056 and all of Mississippi, Montana, Nebraska, New Hampshire, New Mexico and plenty of other states are set at 1.000.

The 2022 PFS conversion factor is $34.6062.

The RBRVS fee schedule applies to:

- Physicians (including limited license practitioners)
- Services "incident to" physician services
- Radiology services (including MRI)
- Outpatient physical, speech language pathology and occupational therapy
- Other diagnostic tests (with the exception of clinical laboratory tests)
- Non-physician practitioners, but at reduced rates (generally limited to 85% of the physician fee schedule amount

The fee schedule also limits reimbursement to physician's assistants, nurse practitioners, clinical nurse specialists, nurse midwives, and certified registered nurse anesthetists, who receive certain percentages of the fee schedule amount. For example, a nurse midwife receives only 65% of the fee schedule.

Physician Work RVUs

The work RVUs for a diagnostic colonoscopy are more than twice the work RVUs for an intermediate office visit because the colonoscopy requires more physician time and effort than the visit. A diagnostic colonoscopy is estimated to require 75 minutes of physician time, which includes 30 minutes to prepare for the procedure and 15 minutes after the procedure. The time actually performing the colonoscopy - termed the intra-service time - is estimated to be 30 minutes. In contrast, an intermediate office visit is estimated to take about 40 minutes of physician time. This is comprised of 5 minutes before and 10 minutes after seeing the patient, and 25 minutes of intra-service time. The intra-service time for the colonoscopy is weighted more heavily than the intra-service time for the office visit to reflect the higher skill and effort and associated stress of providing the procedure.

National Median work RVUs for Select Specialties (based on 2015 data):

Cardiologists	7,413	OB/GYN	6,853
Dermatologists	7,329	Oncologists	4,788
ER Physicians	9,906	Orthopedic Surgeons	7,848
Family Medicine	4,908	Pediatricians	5,299
General Surgeons	6,736	Psychiatrists	4,079
Internal Medicine	4,891		

wRVUs and Physician Compensation

Practices typically use wRVUs to gauge physician productivity and determine physician compensation. To arrive at a compensation amount, a practice multiplies the number of wRVUs the doctor generates by its own conversion factor. The conversion factor typically is determined by dividing the national median compensation for a specialty by the median number of work RVUs for that specialty, data for which can be obtained from the MGMA or American Medical Group Association. To determine a productivity incentive bonus, the practice may pay each physician a bonus tied to the number of wRVUs generated over a base number, such as 2000 RVUs.

J. CMS Manual System.

The CMS Manual System is used by CMS program components, partners, contractors and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models and directives. There are 26 online (internet-only) manuals and three paper-based manuals (which are also available online).

The Medicare Claims Processing Manual (Publication 100-02) is the primary resource for Medicare coverage and payment for physician services.

- Chapter 12 provides claims processing instructions for physician and nonphysician practitioner services.
- Chapter 13 describes billing and payment for radiology services.
- Chapter 16 outlines billing and payment under the laboratory fee schedule.
- Chapter 17 provides a description of billing and payment for drugs.
- Chapter 18 describes billing and payment for preventive services and screening tests.
- Chapter 23 includes the Medicare Physician Fee Schedule format and payment localities and identifies services that are paid at reasonable charge rather than

based on the fee schedule.

- Chapter 26 provides guidance on completing and submitting Medicare claims.

The Medicare Manual Pub 100-1, Medicare General Information, Eligibility, and Entitlement Manual, Chapter 5, provides definitions for the following: Physician; Doctors of Medicine and Osteopathy; Dentists; Doctors of Podiatric Medicine; Optometrists; Chiropractors (but only for spinal manipulation); and Interns and Residents.

The Medicare Benefit Policy Manual, Chapter 15, provides coverage policy for the following services. Telephone services; Consultations; Patient initiated second opinions; and Concurrent care.

- **Note that CMS manuals are policy statements, not binding authority.** Medicare instructions may serve as a guide in determining Medicare coverage criteria and payment authority but have no binding effect on CMS. CMS is free to make coverage decisions in accordance with applicable rules and regulations, regardless of whether the criteria in the Manual instructions are met. It is the implementing regulations that establish the standards for coverage under the Medicare program which are binding on providers.

- *But see* the Garland Memo, issued by Attorney General Merrick Garland on July 1, 2021, which provides that while "guidance documents do not bind the public," do not "have the force and effect of law," and "an agency guidance document by itself never forms the basis of an enforcement action," the Garland Memo nonetheless authorizes the Department of Justice (DOJ) to make increased use of guidance in court. Now, in particular, "[t]o the extent guidance documents are relevant to claims or defenses in litigation, [DOJ] attorneys are free to cite or rely on such documents as appropriate" in False Claims Act matters or those involving the vast array of other laws DOJ enforces.

VIII. Alternative Payment Models.

A. Types of Alternative Payment Models.

1. Accountable Care Organizations.

Accountable care organizations (ACOs) are networks of doctors, hospitals, and other health care providers that share responsibility for coordinating care and meeting health care quality and cost metrics for a defined patient population.

Although ACO-like delivery and payment arrangements gradually evolved among private health care providers and insurers over the last decade, the ACO movement is strongly associated with the Medicare program. The Patient Protection and Affordable Care Act of 2010 (ACA, also known as "Obamacare") codified the ACO model into law, creating the Medicare Shared Savings Program (MSSP), to assess whether this new framework could offer higher quality care at a lower cost. The private sector has also implemented several ACO variations.

Participation in Medicare ACO programs is voluntary. ACOs must accept responsibility for at least 5,000 Medicare FFS patients and participate for at least three years. Medicare ACOs use some variation of a shared savings model with CMS, which financially rewards providers that improve quality on certain metrics while decreasing spending. To earn shared savings, participating ACOs must meet 33 quality measures related to patient and caregiver experience, care coordination, patient safety, preventive health, and at-risk populations. ACOs also must have annual per-beneficiary Medicare expenditures below the CMS-established benchmark for their defined beneficiaries. In some cases, Medicare ACOs financially penalize providers who fail to meet quality and cost metrics.

While many private sector ACOs incorporate aspects of a shared savings model, they are more likely to experiment with ACO variations and include other APMs. Most private ACOs offer financial incentives tied to established quality measures, consist of three-to-five-year programs, and institute shared responsibility for 5,000 or more individuals. Types of private ACO contracts include: 1) Shared Savings Contracts (One-Sided Model), which reward providers with bonuses for meeting quality measures and reducing health spending, but do not penalize them if they fail to achieve savings; 2) Shared Risk Payment Model (Two-Sided Model), which holds providers accountable for both bonuses and penalties; and 3) Partial Capitation, which allows providers experienced in coordinated care to transition towards population-based alternative payment systems. Most private sector ACOs operate within the one-sided risk framework.

MSSP Waivers

The Medicare Shared Savings Program (MSSP) has offered participating hospitals and physicians a series of waivers to shield them from the legal risks associated with ACO formation. Affording protection from fraud and abuse and antitrust enforcement, the waivers were designed to facilitate provider involvement by allowing a variety of organizational arrangements that ordinarily may be prohibited. There are five waivers available: the Pre-Participation Waiver, the Participation Waiver, the Shared Savings Waiver, the Compliance with Stark Law Waiver, and the Patient Incentive Waiver.

• The Pre-Participation Waiver enables an ACO participant or provider, like a hospital, to fund ACO development for the benefit of the ACO participants, including referring physicians,

without the risk of liability under certain federal fraud and abuse laws, including Stark Law, anti-kickback statutes, gainsharing, and beneficiary inducement civil monetary penalties.

• The Participation Waiver can be used to allow an ACO participant or provider/supplier to undertake certain actions for the ACO that might otherwise implicate the federal fraud and abuse laws.

• The Shared Savings Waiver essentially allows for shared savings received by the ACO to be applied in virtually any manner, including distributions to outside parties

• The Compliance with Stark Law Waiver protects arrangements meeting a Stark Law exception from liability under the anti-kickback laws or gainsharing civil monetary penalties.

• The Patient Incentive Waiver allows an ACO to offer to its beneficiaries certain non-monetary preventive items or services.

• On October 20, 2011, the Federal Trade Commission and Department of Justice (the "Agencies") issued a final policy statement on ACOs participating in the MSSP. Significantly, the Agencies eliminated mandatory antitrust review of certain ACOs seeking to participate in the MSSP. The Policy Statement identifies five categories of conduct that, under certain circumstances, may raise competitive concerns and, therefore, are likely to draw Agency scrutiny. Irrespective of Primary Service Areas (PSA) shares (high or low), the Agencies caution against the exchange of competitively sensitive information among ACO participants that could facilitate collusion among ACO participants in the sale of competing services outside of the ACO.

Value-Based Safe Harbors and Exceptions to the Anti-kickback Statute and Stark Law

On December 2, 2020, HHS issued two final rules which modified the anti-kickback statute, the civil monetary penalties law, and the Stark Law, designed to facilitate ACOs by providing greater flexibility to providers engaged in value-based purchasing arrangements. These final regulations include new AKS safe harbors for value-based arrangements, patient engaged and support arrangements, CMS-sponsored models, and cybersecurity, as well as modifications to the EHR and ACO beneficiary incentive safe harbors. The regulations also provide flexibility under the Stark Law for non-abusive business practices and will markedly change the regulatory fraud and abuse landscape for "value-based" arrangements:

(i) The HHS Office of the Inspector General (OIG) published a final rule that introduces new safe harbor protections under the federal Anti-Kickback Statute (AKS) for certain coordinated care and risk-sharing value-based arrangements between or among clinicians,

providers, suppliers, and others that squarely meet all safe harbor conditions.

(ii) CMS published a final rule that finalizes similar exceptions to the Physician Self-Referral Law (Stark Law) for certain value-based compensation arrangements between or among physicians, providers, and suppliers.

To foster the transition to value-based care, HHS promulgated various waivers of the AKS, the Stark Law, and civil monetary penalty (CMP) laws in connection with these CMS-driven innovation models. This reflected a recognition that many traditional fraud and abuse concerns, such as provider overutilization, are mitigated when payments are tied to value instead of volume.

As discussed in the MSSP section above, prior CMS waivers were tied to specific CMS models. Value-based arrangements in the commercial setting -- or otherwise outside of the scope of specifically waived Medicare and Medicaid models -- remained subject to the Stark Law and AKS under a traditional regulatory analysis based on long-standing safe harbors and exceptions. These safe harbors and exceptions, however, have traditionally been ill-suited to encapsulate innovative value-based arrangements.

These final rules introduce an entirely new framework for structuring permissible arrangements and affiliations between and among health care providers and payors. The new definitions, exceptions, and safe harbors that, together, are designed to play a central role toward innovating care coordination and health care payment models for years to come. Through the final rules, CMS and the OIG offer new pathways for providers and payors to come together in innovative ways, without fear of violating fraud and abuse regulations, for both governmental and nongovernmental value-based arrangements.

These safe harbors and exceptions are intended to cover a broad array of arrangements. In a manner of thinking, the final rules reflect an opportunity for payors and providers to "design their own model" through selecting, for example, the patient populations, value-based purposes and activities, quality measures, payment methodologies, referral requirements, and other components of an arrangement without these parameters being prescribed or narrowly defined. At the same time, however, CMS and OIG have included a robust set of requirements and safeguards within each of the new exceptions and safe harbors, which help ensure that the arrangements are structured to drive providers toward clear value-based goals.

For arrangements that are designed and implemented to fit within the parameters set forth in the final rules, providers will be able to take advantage of operating outside the purview of many traditional fraud and abuse safeguards. Of particular note, several of the new safe harbors and

exceptions:

- Do not contain a requirement that an arrangement be set at fair market value.
- Do not require that compensation or other remuneration under an arrangement be set in advance.
- Do allow for directed referrals of patients to specific providers (so long as a series of conditions and exceptions are accounted for).
- Do not contain a broad prohibition on remuneration under an arrangement taking into account the volume or value or referrals.

Notwithstanding the complexity and number of requirements created by the final rules, these value-based safe harbors and exceptions ultimately represent a major regulatory shift that recognizes the reduced need for aspects of the AKS and Stark Law that were designed in part to prevent overutilization. CMS's and OIG's rules each recognize the lessened need for some of the regulations when providers are bearing financial risk and therefore have a financial disincentive for increasing utilization. The new rules will offer providers, payors, and other stakeholders the opportunity to unlock a wide range of new innovative arrangements with greater flexibility under the fraud and abuse laws.

2. Bundled Payments.

Under a bundled payment arrangement, payers compensate providers with a single payment for an episode of care, which is defined as a set of services delivered to a patient over a specific time period. This model aims to incentivize providers to improve care coordination, limit costly and unnecessary services, and reduce variations in care not tied to patient care quality and outcomes. By providing one single payment for various providers, bundled payments seek to promote a team-based approach to care. Though bundled payments differ based on the patients' illnesses and conditions and tend to reflect the average costs of the treatments involved in an episode of care, they do not typically vary with the explicit number or mix of services provided to any individual patient. In most models, participating providers share in savings if their actual expenditures are below the bundled payment amount.

Early Medicare Initiatives

Both Medicare and private payers have utilized bundled payment arrangements with providers for narrow sets of services, including, for example:

• The PROMETHEUS Payment model -- launched in 2006 with three initial pilot sites -- it had, prior to its demise in May 2011, grown to cover 21 episodes of care bundles, including

heart attacks, hip and knee replacements, diabetes, asthma, congestive heart failure, and hypertension. The project faced substantial implementation challenges, primarily because of the complexity of the payment model and the fact that it built on the then-existing fee-for-service payment system.

• The Medicare Acute Care Episode Demonstration (ACE) was a three-year demonstration project commencing in 2009 where CMS provided bundled payments to providers at five health systems for all Part A and B services relating to an episode of care for nine orthopedic and 28 cardiac inpatient surgical services and procedures. This program was unique in that it allowed sharing of Medicare savings with beneficiaries and gainsharing between physicians and facilities.

Comprehensive Care for Joint Replacement

On November 24, 2015, CMS introduced its newest bundled payment initiative: Comprehensive Care for Joint Replacement ("CJR"), which covers hip and knee replacements (called lower extremity joint replacements or "LEJR"). The CJR model holds participant hospitals financially accountable for the quality and cost of a CJR episode of care and incentivizes increased coordination of care among hospitals, physicians, and post-acute care providers. The episode of care begins with an admission to a participant hospital of a beneficiary who is ultimately discharged under MS-DRG 469 (major joint replacement or reattachment of lower extremity with major complications or comorbidities) or 470 (major joint replacement or reattachment of lower extremity without major complications or comorbidities) and ends 90 days post-discharge in order to cover the complete period of recovery for beneficiaries. The episode includes all related items and services paid under Medicare Part A and Part B for all Medicare fee-for-service beneficiaries, with the exception of certain exclusions. The CJR model began on April 1, 2016 and will run through December 31, 2024. As of November 1, 2021, approximately 324 IPPS (inpatient prospective payment system) hospitals in 67 different MSAs (metropolitan statistical areas) are participating in the CJR model.

Providers and suppliers are paid under the existing payment systems in the Medicare program for episode services throughout the year. Every year, the model will set Medicare target episode prices for each participant hospital that includes payment for all related services received by eligible Medicare fee-for-service beneficiaries who have LEJR procedures at that hospital. Following the end of a model performance year, actual episode spending for a participant hospital will be compared to the applicable Medicare target episode prices for that hospital. Depending on the participant hospital's quality and episode spending performance, the hospital may receive an additional payment from Medicare or, beginning in the second year of the model, may need to repay Medicare for a portion of the episode spending.

The model allows participant hospitals to enter into financial arrangements with certain types of providers and suppliers (SNFs, long-term care hospitals, HHAs, inpatient rehabilitation facilities, physician and non-physician practitioners, and outpatient therapy providers) who are engaged in care redesign with the hospital and also furnish services to Medicare beneficiaries during a CJR episode. Those arrangements allow participant hospitals to share, subject to the limitations outlined in the rule, with these third-party providers and entities the following: reconciliation payments, internal cost savings, and the responsibility for repayment to Medicare.

Participation in CJR had been mandatory for all IPPS providers located in the 67 MSAs selected for the CJR model, but in an amendment to the final rule, as of October 1, 2021, only hospitals in one of the 34 required metropolitan statistical areas (MSAs) and not designated as low volume or rural are required to participate in the CJR.

• The CJR model is eligible to be an Advanced APM.

Bundled Payments for Care Improvement-Advanced

1. Bundled Payments for Care Improvement.

The most prominent Medicare bundled payments initiative is the Medicare Bundled Payments for Care Improvement (BPCI) initiative, established by the CMS Innovation Center. The project involves four different models of care and payment for participating providers. Under the BPCI initiative, organizations entered into payment arrangements that included financial and performance accountability for episodes of care. BPCI commenced in April 2013 and ended on September 30, 2018. It is useful to understand BPCI in order to appreciate its successor, BPCI-Advanced.

• In Model 1, the episode of care was defined as the inpatient stay in the acute care hospital. Medicare paid the hospital a discounted amount based on the payment rates established under the Inpatient Prospective Payment System (IPPS) used in the original fee-for-service (FFS) Medicare program. Medicare continued to pay physicians separately for their services under the Medicare Physician Fee Schedule (PFS). The first cohort of Awardees in Model 1 began in April 2013 and concluded on March 31, 2016.

• Model 2 and Model 3 involved a retrospective bundled payment arrangement where actual expenditures are reconciled against a target price for an episode of care. In Model 2, the episode includes the inpatient stay in an acute care hospital plus the post-acute care and all related services up to 90 days after hospital discharge. In Model 3, the episode of care is triggered by an acute care hospital stay but begins at initiation of post-acute care services with a skilled nursing facility, inpatient rehabilitation facility, long-term care hospital or home health

agency. Under these retrospective payment models, Medicare continued to make fee-for-service (FFS) payments; the total expenditure for the episode was later reconciled against a bundled payment amount (the target price) determined by CMS. A payment or recoupment amount was then made by Medicare reflecting the aggregate expenditures compared to the target price.

• In Model 4 (which is now winding down), CMS makes a single, prospectively determined bundled payment to the hospital that encompasses all services furnished by the hospital, physicians, and other practitioners during the episode of care, which lasts the entire inpatient stay. Physicians and other practitioners submit "no-pay" claims to Medicare and are paid by the hospital out of the bundled payment.

On January 9, 2018, CMS announced that BPCI would be replaced by BPCI-Advanced.

2. Bundled Payments for Care Improvement-Advanced (BPCI-Advanced).

Unlike the original BPCI, which was comprised of four broadly defined models with different payment models and risk tracks, BPCI-Advanced consists of a single payment model and risk track for all clinical episodes, which begin on the first day of the triggering inpatient stay or outpatient procedure and extend through the 90-day period starting on the day of discharge from the inpatient stay or the completion of the outpatient procedure, as applicable. BPCI-Advanced uses a retrospective bundled payment approach, in which usual fee-for-service (FFS) payments are made to participating, Medicare-enrolled providers and suppliers, and the total FFS payments for each clinical episode are then retrospectively reconciled against a predetermined target price. Other key differences include simplified precedence rules and risk adjustment at both the provider and beneficiary level. Aside from these differences, BPCI-Advanced is in many respects a continuation of the original BPCI.

• Unlike BPCI, BPCI-Advanced is an Advanced APM.

• *Participants.* For purposes of BPCI-Advanced, a "Participant" is an entity that enters into a BPCI-Advanced Model Participation Agreement with CMS to participate in the model. There are two categories of Participants under BPCI-Advanced: "Convener Participants" and "Non-Convener Participants."

• Convener Participants bring together and coordinate multiple downstream "Episode Initiators," which must be either physician group practices ("PGPs") or acute care hospitals ("ACHs"). In addition to serving this coordinating function, Convener Participants bear and apportion financial risk on behalf of and among their Episode Initiators.

• Non-Convener Participants are Episode Initiators (*i.e.*, PGPs and ACHs) that

bear only their own financial risk, and do not bear risk on behalf of any downstream Episode Initiators. Both Convener Participants and Non-Convener Participants may enter into agreements with individual downstream physicians and non-physician practitioners ("Participating Practitioners") who furnish care during clinical episodes.

• *Clinical Episodes.* BPCI-Advanced includes 105 Medicare Severity-Diagnosis Related Groups (MS-DRGs), grouped into 29 inpatient clinical episode categories, as well as three outpatient clinical episode categories - namely, Percutaneous Coronary Intervention, Cardiac Defibrillator, and Back & Neck (except Spinal Fusion) - each identified by 30 HCPCS codes (collectively, "Clinical Episodes"). Participants may elect to be held accountable for any of the 29 inpatient and three outpatient Clinical Episodes included in the model but will not be allowed to add or drop Clinical Episodes except as expressly permitted by CMS.

• *Reconciliation and Gainsharing.* CMS conducts semi-annual reconciliations against prospectively determined Clinical Episode-specific target prices, adjusted by CMS based on the Participant's actual patient case mix, to calculate the final target price (the "Target Price"). If, during the semi-annual reconciliation process, all non-excluded Medicare FFS expenditures for a Clinical Episode for which the Participant has opted in are less than the final Target Price for that Clinical Episode, a positive reconciliation amount results. (By contrast, if all non-excluded Medicare FFS expenditures for a Clinical Episode are greater than the final Target Price, this results in a negative reconciliation amount.) CMS nets reconciliation amounts across all Clinical Episodes attributed to each Episode Initiator to calculate a total reconciliation amount, which CMS then adjusts according to certain pre-defined quality criteria (as described below).

• For Convener Participants, CMS nets the quality-adjusted reconciliation amounts across all of the Participant's Episode Initiators to calculate either the "Net Payment Reconciliation Amount" ("NPRA") (if positive) or a "Repayment Amount" (if negative). These reconciliation payments, both to Participants from CMS, and from Participants to CMS, are capped at +/-20% of the volume-weighted sum of the final Target Prices across all Clinical Episodes netted for each Episode Initiator within the Performance Period.

• Participants may also enter into financial arrangements with "NPRA Sharing Partners" (such as Participating Practitioners, PGPs, ACHs, and ACOs) to share NPRAs or to apportion the responsibility for Repayment amounts, subject to a cap set at 50% of the total Medicare FFS expenditures included in Clinical Episodes attributed to the Participant for which the NPRA or Repayment Amount was calculated.

• *Quality Measures and MACRA.* As noted above, CMS will adjust the total reconciliation amounts to reflect an Episode Initiator-specific "Composite Quality Score" ("CQS"), which CMS will calculate based on the Episode Initiator's scores on the applicable set

of quality measures.

• While CMS may adjust the specific set of quality measures on an annual basis, the measures will include both process (*e.g.*, advance care plan) and outcome (*e.g.*, all-cause hospital readmissions) measures.

• For the first two model years, the amount by which a reconciliation amount may be adjusted based on the CQS is capped at 10 percent.

• *Fraud and Abuse Waivers.* As with BPCI, fraud and abuse waivers were issued for BPCI-Advanced pursuant to the Secretary's authority under Section 1115A of the Social Security Act, 42 U.S.C. § 1315a.

Fraud and Abuse Waivers for Select CMS Models and Programs

Section 1115A(d)(1) of the Social Security Act (the Act) authorizes the Secretary of Health and Human Services to waive certain fraud and abuse laws as necessary solely for purposes of testing payment and service delivery models developed by the Center for Medicare and Medicaid Innovation (the Innovation Center). In connection with each of the Innovation Center models listed below, unique waivers of certain fraud and abuse laws have been made generally available. Note, however, not all model-specific waivers are necessarily available to all participants in a given model. Individuals or entities seeking waiver protection should keep in mind that a waiver will apply to their arrangement(s) only if they are eligible to use the waiver and all conditions of the waiver are met.

HHS has issued fraud and abuse waivers and related guidance documents in connection with the following programs:

- Pioneer Accountable Care Organization (ACO) Model
- Bundled Payment for Care Improvement (BPCI) Models
- Health Care Innovation Awards (HCIA) Round Two
- Comprehensive ESRD Care (CEC) Model
- Comprehensive Care for Joint Replacement (CJR) Model
- Next Generation ACO Model
- Oncology Care Model (OCM)
- Part D Enhanced Medication Therapy Management (MTM) Model
- Part D Payment Modernization Model
- Maryland All-Payer Model Care Redesign Program
- Maryland Total Cost of Care Model Care Redesign Program
- Medicare Advantage Value-Based Insurance Design Model
- Medicare Diabetes Prevention Program (MDPP) Expanded Model

- Bundled Payments for Care Improvement Advanced (BPCI Advanced) Model
- Vermont All-Payer ACO Model Vermont Medicare ACO Initiative
- Part D Senior Savings Model
- Comprehensive Kidney Care Contracting (CKCC) Options of the Kidney Care Choices Model
- Global and Professional Options of the Direct Contracting Model
- Primary Care First (PCF) Component of the Primary Care First Model
- Medicare Shared Savings Program

More information on fraud and abuse waivers for select CMS models and programs can be found at:

https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html#Oncology%20Care%20Model%20(OCM)

3. Pay For Performance.

"Pay-for-performance" (P4P) is a term used to refer to those payment models aimed at improving the quality, efficiency and the overall value of health care. In P4P arrangements, providers are reimbursed based on whether they achieve a predetermined set of quality measures.

The most common form of financial incentive in a P4P program is a bonus payment - an amount paid to a provider in addition to his or her usual fee for a particular service once that provider meets certain quality goals. Other financial incentives may include withholds, penalties, fee schedule adjustments, per-member payments, payments for the provision of a particular service, lack of payment for poor performance, shared savings, quality grants or loans, or payment for participation in certain activities or for reporting on certain activities, such as reporting of outcome measures for hospitals.

4. Patient Centered Medical Homes.

The patient centered medical home (PCMH) model facilitates the coordination of care through a patient's primary care physician. The PCMH model integrates mental health and specialty services and involves a team-based approach consisting of physicians, nurses and medical assistants, pharmacists, nutritionists, social workers and care coordinators. Stating the exact definition of a PCMH is difficult as the model is continually evolving. Four major primary care societies, however, have endorsed the description provided in the Joint Principles of the Patient-Centered Medical Home, which outline the general characteristics of a PCMH as: personal physician care, physician-directed medical practice, whole person orientation, coordinated and/or integrated care, high quality and safety in care, enhanced access to care, and payment that supports enhanced services.

Payments to PCMHs differ from those under the traditional Fee for Service (FFS) system in several ways. PCMH programs typically use a combination of the following care coordinating and performance-based payments on top of existing FFS payments: 1) enhanced FFS evaluation and management payments; 2) additional codes for medical home activities within FFS payments; 3) per member per month medical home activities within FFS payments; and 4) risk-adjusted, comprehensive per member per month payments.

Comprehensive Primary Care Initiative-Plus (CPC+)

The most prominent Medicare PCMH initiative was the Medicare Comprehensive Primary Care Initiative-Plus (CPC+) program, established by the CMS Innovation Center.

Background.

On April 11, 2016, the CMS Innovation Center announced that it would implement a new payment demonstration called Comprehensive Primary Care Plus (CPC+) beginning in January 2017 and ending on December 31, 2021. CPC+ was a public-private partnership, in which 2,610 primary care practices were supported by 52 aligned payers in 18 regions. CPC+ sought to improve quality, access, and efficiency of primary care. Primary care practices participated in one of two "Tracks" and the payment model differed in each track. Practices in both tracks made changes in the way they delivered care, centered on key Comprehensive Primary Care Functions: (1) Access and Continuity; (2) Care Management; (3) Comprehensiveness and Coordination; (4) Patient and Caregiver Engagement; and (5) Planned Care and Population Health.

Comprehensive Primary Care Initiative-Plus (CPC+) Program Model Details

Primary care practices participated in one of two "Tracks" and the payment model differed in each track.

"Track 1" Payment Model. Primary care practices in "Track 1" of the CPC+ initiative received three categories of payment:

1. **Current FFS:** The practice can continue to bill for and be paid at standard Medicare rates for all CPT codes on the Physician Fee Schedule except for the Chronic Care Management fee (CPT 99490).

2. **Care Management Fee (CMF):** In addition to FFS payments, the practice received a CMF payment each month for each Medicare patient, which averaged $15 per beneficiary per month. The actual amount of the CMF payment will be different for different patients depending on the risk tier in which the patient is classified using the

CMS Hierarchical Condition Category (HCC) risk adjustment system:

Tier 1: $6 for patients with an HCC score in the first (lowest) quartile among Medicare beneficiaries
Tier 2: $8 for patients with an HCC score in the second quartile
Tier 3: $16 for patients with an HCC score in the third quartile
Tier 4: $30 for patients with an HCC score in the fourth quartile

3. Performance-Based Incentive Payment: In addition to FFS payments and the Care Management Fee, the practice received a $2.50 payment each month for each Medicare patient. The practice would have to return all or part of this payment to Medicare depending on the practice's performance on utilization and quality measures:

Quality-Based Incentive: the practice's ability to keep one half ($1.25) of the payment would depend on whether the practice meets annual performance thresholds on quality and patient experience measures. The practice would have to return between 0% and 100% of this payment based on its percentage score on the performance measures.

Utilization-Based Incentive: the practice's ability to keep the other half ($1.25) of the payment would depend on whether the practice meets annual performance thresholds on measures of inpatient admissions and emergency department visits for its patients and also on whether the practice met minimum standards of quality.

"Track 2" Payment Model. Primary care practices in "Track 2" of the CPC+ initiative received four categories of payment:

1. Reduced FFS: The practice can continue to bill for all CPT codes except for the Chronic Care Management fee (CPT 99490). The amount of payment for Evaluation & Management Services (E&M) codes (i.e., office visits) would be reduced by either 40% or 65%. (Practices would be divided into two groups with different reductions.) These reductions would be phased in between 2017 and 2019, with three options available for how quickly the phase-in would occur. All other CPT codes would be paid at standard rates.

2. Comprehensive Primary Care Payment (CPCP): The practice would receive a per-beneficiary per month payment, paid quarterly. The amount of this payment would differ by practice and would be equal to either 40% or 65% of the revenues the practice had received for E&M services prior to the start of the CPC+ program (in order to offset the 40% and 65% reductions in E&M payments) plus 10%. The amount of this payment could be reduced if the practice's patients increase their use of primary care from physicians who are not part of the practice receiving the CPCP.

3. Care Management Fee (CMF): In addition to FFS payments and the CPCP, the practice will receive a CMF payment each month for each Medicare patient, which is expected to average $28 per beneficiary per month. The actual amount of the CMF payment will be different for different patients depending on the risk tier in which the patient is classified using the CMS Hierarchical Condition Category (HCC) risk adjustment system and diagnosis:

Tier 1:	$9 for patients with an HCC score in the first (lowest) quartile among Medicare beneficiaries
Tier 2:	$11 for patients with an HCC score in the second quartile
Tier 3:	$19 for patients with an HCC score in the third quartile
Tier 4:	$33 for patients with an HCC score in the 75-89% range of the distribution
Complex:	$100 for patients with an HCC score in the top (highest) decile 10% OR a diagnosis of dementia regardless of their HCC score

4. Performance-Based Incentive Payment: In addition to FFS payments and the Care Management Fee, the practice would receive a $4.00 payment each month for each Medicare patient. The practice would have to return all or part of this payment based on its performance on utilization and quality measures:

Quality-Based Incentive: the practice's ability to keep one half ($2.00) of the payment would depend on whether the practice meets annual performance thresholds on quality and patient experience measures. The practice would have to return between 0% and 100% of this payment based on its percentage score on the performance measures.

Utilization-Based Incentive: the practice's ability to keep the other half ($2.00) of the payment would depend on whether the practice meets annual performance thresholds on measures of inpatient admissions and emergency department visits for its patients and also on whether the practice met minimum standards of quality.

CPC+ qualifies as an "Advanced Alternative Payment Model" and that physicians participating in CPC+ at the minimum levels required in the law and regulation would be exempt from the Merit-Based Incentive Payment System (MIPS), qualify for 5% lump sum bonuses from 2019 to 2024, and receive higher annual fee for service payment updates beginning in 2026.

As noted above CPC+ ended on December 31, 2021. Practices that were enrolled in CPC+ were

given the option of applying by May 21, 2021, to participate in Primary Care First (PCF) or returning to traditional fee-for-service (FFS).

Primary Care First (PCF)

PCF expands the care management principles of the CPC+ program to include redesign of physician time and places an emphasis on hospital utilization. Its design encourages participation from practices that have built the infrastructure required to succeed in CPC+ and are ready to assume higher levels of responsibility for patient outcomes and expand their efforts to include modifying the physician's day.

While PCF builds on the learnings from CPC+, it is also a riskier model. CPC+ offers a direct "plus-up," in the form of a quarterly payment, for practices to add care management and other wrap-around services, but PCF does not make the same direct investments. PCF primarily changes how physician practices are paid and offers the opportunity to increase overall revenue if the practice excels at lowering hospitalizations.

PCF Payment Mechanisms

In PCF, the amount that practices receive from traditional FFS payments on Evaluation and Management (E&M) services will be drastically reduced. Instead of getting paid $92 for an E&M visit or $133 for an Annual Wellness Visit (AWV), practices will receive a flat-visit-fee of $40 for any E&M, Transitional Care Management (TCM), AWV, or Advance Care Planning (ACP) visit, plus a per beneficiary per month (PBPM) that ranges from $28 - $175 based on the practice's average Hierarchical condition category (HCC) risk score for attributed beneficiaries, also referred to as the practice's "risk group bucket." This monthly payment differs from the CPC+ care management fee in that it is the same for all patients and is not stratified by individual patient risk scores like it was in CPC+.

PCF practices will also receive a performance-based adjustment (PBA) that ranges from -10 to 50 percent of their flat-visit-fee and PBPM payments. The PBA will be based on the practice's performance on four quality measures, plus their performance on Acute Hospital Utilization compared to a national benchmark, a regional benchmark, and their previous selves (continuous improvement). Additionally, starting in year two, practices will be subject to a leakage adjustment that accounts for primary care visits attributed patients have outside of the PCF practice. More information on the difference between CPC+ and PCF payment mechanisms can be found in Table 1.

B. Medicare Access & CHIP Reauthorization Act of 2015 (MACRA).

MACRA is presented below in separate abbreviated and detail discussions.

MACRA - Summary Description.

What is MACRA?

MACRA, enacted in 2015 with broad bipartisan support, repealed the unpopular sustainable growth rate formula for setting the Medicare Part B physician fee schedule. In its place, there were modest annual increases of 0.5 percent in the fee schedule through 2019, no change from 2020 through 2025, and then another modest annual increase of 0.25 percent or 0.75 percent beginning in 2026 based on physician participation in one of two tracks in the new CMS Quality Payment Program (QPP). The two QPP tracks are the merit-based incentive payment system (MIPS) and the advanced alternative payment model (Advanced APM).

- Merit-Based Incentive Payment System (MIPS).

MIPS is the "default" track under MACRA. Under MIPS, Medicare Part B payments are based on physician performance in four domains:

(1) quality (replaces the physician quality reporting system (PQRS));
(2) advancing care information (replaces meaningful use);
(3) cost (replaces the value-based modifier program); and,
(4) improvement activities (a new domain that considers activities which support aims within health care, such as improving delivery, care coordination, engaging beneficiaries, population management, and health equity)

Physicians may report their performance individually or as part of a group. Depending on performance, which is tied to a weighted average in these four domains, MIPS physicians were subject to payment adjustments of up to 4 percent (positive or negative) from the baseline Medicare Part B fee schedule in calendar year 2019 based on performance in CY 2017. The payment adjustment threshold was increased (positive or negative) to 5 percent in 2020, 7 percent in 2021, and 9 percent in 2022 and the following years.

In other words, beginning in this year (2022), the potential spread in payment between the lowest-performing physicians and the highest-performing physicians could be up to 18 percent. An additional 10 percent bonus may be available to clinicians with exceptional performance, though CMS has indicated that payout of that bonus is unlikely.

Not all physicians are required to participate in MIPS. Physicians who are in their first year as a

Medicare Part B participant are exempt, as are physicians reporting individually who have $90,000 or less in allowed Part B charges or 200 or fewer Medicare patients, or who are reporting as a group and who collectively satisfy these same low-volume thresholds.

- Advanced Alternative Payment Models (APMs).

  Advanced APMs are special alternative payment models designated by CMS that:

  (1) require participants to use certified electronic health record (eHR) technology
  (2) provide payment based on quality measures comparable to MIPS quality metrics; and
  (3) qualify as a medical home model under CMS Innovation Center authority OR require participating APM entities to bear more than a nominal amount of financial risk for monetary losses.

Physicians who elect to participate in an advanced APM forego MIPS reporting and reimbursement. Instead, such physicians are subject to the reporting, performance, and payment mechanisms underlying the specific advanced APM in which they participate, and additionally receive an annual lump sum bonus of 5 percent of their Medicare Part B payments in 2019 to 2024.

Data from 2018, which was reported by CMS in 2020, indicates that the number of physicians receiving Medicare payments through risk-based models sharply increased in 2018, while the much larger number for whom payment is based on quality-measure performance started to decline. This means that MIPS lost participants while APMs gained participants. This data shows:

- APM participation increased by 84% to more than 183,000.
- MIPS participation decreased by 5% to nearly 890,000.
- Of physicians paid through MIPS, 97% received a bonus payment of as much as 1.68%.
- Of physicians paid through MIPS, 2% were dealt payment cuts of as much as 5%.

MACRA - Detailed Description.

On April 16, 2015, President Obama signed into law legislation (H.R. 2, "Medicare Access and CHIP Reauthorization Act of 2015" or "MACRA") that permanently replaces the sustainable growth rate ("SGR") formula used for calculating payments to physicians under the Medicare Physician Fee Schedule ("MPFS"), and replaced with the two complex payment reforms:

- Merit-Based Incentive Payment System ("MIPS")
- Alternative Payment Models ("APMs")

Congress has established a three-phased approach to transitioning away from the SGR and basing physician payments instead on quality performance and participation in APMs.

Phase 1. Five-Year Period of Consistent Updates.

The first phase is a period of consistency in Medicare physician payments, as CMS ramped up to implement the new payment system. MACRA provided for annual updates of 0.5% for a five-year period, from July 1, 2015, through the end of 2019. This moves physician payments away from the SGR formula, which was created to limit Medicare expenditures for physician services if such payments exceeded an annual spending target tied to overall economic growth.

Phase 2. Opportunity for Payment Adjustments or Bonus Payments.

In the second phase, there will be no annual updates to the Medicare payment rates from 2020 through the end of 2025. However, physicians have two opportunities for payment adjustments or bonus payments: (1) through participation in the MIPS program, or (2) through participation in a qualifying APM.

Merit-Based Incentive Payment System.

For payments on or after January 1, 2019, physicians will have the opportunity to receive adjustments to their traditional fee-for-service ("FFS") Medicare payments through participation in MIPS, an incentive-based payment program that rewards quality performance related to four assessment categories:

- Quality of care measures
- Resource use
- Meaningful use of electronic health records ("EHRs")
- Clinical practice improvement activities

Physicians will receive a positive or negative payment adjustment based on how their composite performance score for each of the four assessment categories compares to a base performance threshold. Namely, physicians will be eligible for incentive payments if they achieve high-quality performance and continue to improve their performance annually, when compared to the base performance threshold. Providers falling below the base performance threshold will be subject to negative adjustments at increasing percentages.

Negative payment adjustments are capped at 4% in 2019, 5% in 2020, 7% in 2021, and 9% in 2022 and beyond. Positive payment adjustments, which must be paid out in an amount equal to the total negative payment adjustments across all providers, can reach up to a maximum of three times the annual cap for negative payment adjustments in a particular year (i.e., 12%, 15%, 21%, and 27%, respectively). There also is an opportunity for "exceptional performers" to receive additional incentive payments, up to 10% of their FFS Medicare payments per year. These additional incentive payments for "exceptional performers" will be capped at $500 million per year for each of 2019 through 2024. Physicians who do not report any MIPS quality metrics will automatically be given the lowest score and see the maximum downward adjustment, unless one of the applicable exceptions applies.

Medicare Alternative Payment Models.

Alternatively, physicians who receive a significant share of their revenue through participation in a qualifying APM from 2019 through 2024 will receive an annual lump sum bonus of 5% of estimated MPFS payments for the preceding year. The bonus payment would be in addition to any shared savings bonuses or fees that the physician might receive for participating in the APM.

APMs are defined in MACRA to include models being tested by the Center for Medicare and Medicaid Innovation ("CMMI") (other than health care innovation awards), accountable care organizations ("ACOs") participating in the Medicare Shared Savings Program, models tested under the Health Care Quality Demonstration Program, and other demonstrations required by federal law (such as BPCI-Advanced and CPC+).

Further, qualifying APMs are those that require participating providers to take on "more than nominal" financial risk, report quality measures that are comparable to the measures adopted under MIPS, and use certified EHR technology.

To qualify as an APM participant, providers must meet increasing thresholds for the percentage of their revenue that they receive through qualifying APMs. The APM requirements are phased in as follows:

- In 2019 and 2020, 25% of Medicare payments for covered professional services must be attributable to services furnished through an APM.

- In 2021 and 2022, 50% of Medicare payments for covered professional services must be attributable to services furnished through an APM or 50% of all-payer revenue (of which at least 25% is from Medicare payments for covered professional services) must be attributable to services furnished through an APM.

• In 2023 and beyond, 75% of Medicare payments for covered professional services must be attributable to services furnished through an APM or 75% of allpayer revenue (of which at least 25% is from Medicare payments for covered professional services) must be attributable to services furnished through an APM.

Providers that receive a bonus payment for participation in an APM are excluded from participation in MIPS. Providers that are below but close to the required level of APM revenue also may be exempted from participation in MIPS; however, they will not receive a bonus payment for participation in an APM.

Phase 3. Updates Based on Participation in Alternative Payment Models.

In the third phase, starting in 2026 and subsequent years, annual updates will differ based on whether a physician is participating in an APM that meets certain criteria. Physicians participating in qualifying APMs will receive a 0.75% update, and all other physicians will receive a 0.25% update. This two-track system creates an incentive for physicians to accept risk-based payments, instead of the traditional FFS Medicare payments, because the differential annual update is cumulative from year to year and therefore APMs would be paid increasingly more each year relative to non-APMs.

C. Population Health and Risk-Based Payment Models.

1. *Population Health.*

The term "population health" is widely used, but what does it mean? In the field of public health, population health is generally defined as the health outcomes of a group of individuals, including the distribution of such outcomes within the group.

However, most physicians and health care attorneys do not see the term population health used in a public health context, but in a health insurance context. In the health insurance arena, the term population health is frequently used in conjunction with risk-bearing arrangements. As health insurers consolidate, they need to segregate their enrollees in order to better manage the care of those enrollees; basically, the insurers are shrinking their overall population (millions of lives) into something more manageable (tens or hundreds of thousands of lives) by provider groups who are willing assume some risk for the costs of care for a specific population.

Physicians who participate in population health initiatives will likely be asked to place a portion of their compensation "at risk," received only if costs are reduced and metrics are met.

2. *Risk-Based Payment Models.*

There are a variety of risk-based or budget-based payment models being developed. Risk-based arrangements (i.e., budget-based contracting) payments are predicated on an estimate of what the expected costs to treat a particular condition or patient population should be. This includes capitation, bundled payments, and shared savings arrangements. While health plans will base expected costs on sophisticated and actuarially sound models, physicians need to be sure to understand how these costs were calculated and that they include the total direct and indirect practice expenses and margin.

The onus is on the physician to be able to manage expected utilization and related practice expenses for treatment. Success is based on the practice's ability to control the health care expenses of the patient population so that they do not exceed the budgeted amount. The practice may share in the potential savings as well as any losses. For example, the practice may share in a percentage of any savings (e.g., upside risk); however, if the actual costs of care exceed the target or budgeted costs, the practice may be responsible for a percentage of the difference (e.g., downside risk).

3. *Types of Risks Included in a Risk-Based Payment Model.*

Basically there are two types of risks inherent in a risk-based contract: insurance risk and performance and utilization risk. Insurance risk entails the financial costs of diseases, accidents, or injury spread out over a covered population (i.e., insured members). Carriers of insurance risk (insurance plans, self-insured employers) by state law must have required sufficient financial reserves to cover the insurance risk and, as a result, most providers may not have the necessary financial reserves to fund a commercial insurance program. Physicians should not be required to accept insurance risk (i.e., whether or not a covered member gets ill).

Performance or utilization risk involves managing the rates of utilization of medical services by a defined population. Providers may have greater control over the utilization of services (particularly unnecessary services) as well as the quality and availability of services they provide. Under risk-based contracting, it is most often the performance risk that is shifted to the provider.

Additionally, risk-based models include either or both an upside and downside risk. In an upside risk arrangement, the provider only shares in the savings and not the risk of loss. For example, if the actual total costs of care of patients assigned to a physician's practice are lower than projected budgeted costs, the practice receives a defined percentage of the difference between the actual costs and budgeted costs (shared savings). However, if the actual total costs of care exceed the budget costs, the practice would not be responsible for the difference. In this

scenario, since the practice is only at risk for additional revenue through the shared savings, the practice is only sharing in the upside risk.

In cases where the practice would share in the savings as well as be responsible for a portion of the difference between actual total costs that exceed budgeted costs, the practice would share in the downside risk.

D. Triple Aim.

The launch of the Triple Aim in 2007 by the Institute for Healthcare Improvement provided a framework for categorizing the ongoing multifaceted quality improvement efforts providers are undertaking to achieve consistent, high-quality care. The Triple Aim calls for the simultaneous pursuit of three goals:

a. improving the patient experience of care (including quality and satisfaction);
b. improving the health of populations; and,
c. reducing the per capita cost of health care

The idea is to address all three of the Triple Aim dimensions at the same time. A provider can fulfill the Triple Aim by implementing a system with the following five components:

(1) Focus on individuals and families
(2) Redesign of primary care services and structures
(3) Population health management
(4) Cost control platform
(5) System integration and execution

The Institute for Health Care Improvement believes that many areas of health reform can be furthered and strengthened by Triple Aim thinking, including accountable care organizations (ACOs), bundled payments, and other innovative financing approaches; new models of primary care, such as patient-centered medical homes; sanctions for avoidable events, such as hospital readmissions or infections; and the integration of information technology.

E. Health Disparity, Equality and Equity.

People use many different terms when it comes to accessing healthcare, including health disparity, health equality, and health equity.

1. *Health disparity.*

Health disparity is a difference that affects a person's ability to achieve their best health. Examples of health disparities include race, gender, education, income, disability, geographic location, and sexual orientation. Health disparities create health inequities. Due to their differences or situation, some people do not always have access to the same opportunities to better their health that other people have. Two concepts refer to how to correct these health disparities: health equality and health equity.

2. *Health equality vs. health equity.*

Health equality means everyone has the same opportunities. Examples could include a community center offering free or low-cost checkups to everyone.

Health equity means that people have opportunities based on their needs. An example could be the same health center charging people based on their ability to pay. A person who cannot afford care may receive it for free while another person may pay for the same care.

In short, health equality means everyone receives the same standard, while health equity means everyone receives individualized care to bring them to the same level of health. Health equality is not always preferable. For example, if a clinic offers free checkups every morning, a person who must work during the morning cannot take advantage of this service. While the clinic offers checkups to everyone on the same terms, some people still cannot take advantage of the service. Health equity would involve offering alternative checkup times in the afternoon or evening, so everyone can access the service at a time that suits them.

3. *Examples of health equity.*

Examples of services that promote health equity include:

- Providing health seminars and courses that are specific to the needs of certain ethnic communities and racial groups.
- Providing low-cost services to those living in a low-income household.
- Using mobile health screenings to help those who may not have access to transportation.
- Offering evening or late-night health appointments to those who work long hours and are unable to access care.
- Providing better education, testing, and treatment access to communities particularly impacted by certain conditions or diseases.

4. *Who does not have health equity?*

Groups who do not have health equity are those that are traditionally disenfranchised and discriminated against through no fault of their own. Examples include:

- racial and ethnic minorities
- people living in a low-income household
- members of the LGBTQ+ community

Members of these communities are more likely to experience barriers to care and health, such as violence, low income, and poor living conditions.

IX. Telemedicine.

Before the pandemic, coverage of telehealth services under traditional Medicare was limited to beneficiaries living in rural areas only, with restrictions on where beneficiaries could receive these services and which providers could be paid to deliver them. Soon after the federal government declared a public health emergency due to COVID-19 in early 2020, Congress and CMS expanded traditional Medicare's coverage of telehealth services in order to make it easier for beneficiaries to get medical care and minimize their exposure to coronavirus in health care settings. When the public health emergency ends, however, Medicare's coverage of telehealth services will revert back to the more limited availability that existed before the pandemic, unless policymakers take action to extend the expanded coverage.

A. Telehealth During Covid.

Before the COVID-19 pandemic, coverage of telehealth services under traditional Medicare was limited. Medicare paid for approximately 100 services provided by telehealth, and there were limitations on how these services could be delivered and which beneficiaries could access them. Such limitations do not apply in Medicare Advantage plans, which have flexibility to offer additional telehealth benefits not covered by traditional Medicare outside of the public health emergency. Prior to the pandemic, the utilization of telehealth among traditional Medicare beneficiaries was extremely low, with only 0.3% of traditional Medicare beneficiaries enrolled in Part B using telehealth services in 2016, accounting for only 0.4% of traditional Medicare Part B spending. But during the summer and fall of 2020, about one out of four Medicare beneficiaries (27%, or 14.9 million beneficiaries) reported having a telehealth visit.

Before the public health emergency, telehealth services were generally available only to beneficiaries in rural areas originating from a health care setting, such as a clinic or doctor's

office. Beneficiaries in urban areas were ineligible for telehealth services, and beneficiaries could not receive telehealth services in their own homes.

To make it easier and safer for beneficiaries to seek medical care during the COVID-19 pandemic, the HHS Secretary waived certain restrictions on Medicare coverage of telehealth services for traditional Medicare beneficiaries during the COVID-19 public health emergency, based on waiver authority included in the Coronavirus Preparedness and Response Supplemental Appropriations Act (and as amended by the CARES Act). The waiver, effective for services starting on March 6, 2020, significantly loosened coverage restrictions for telehealth under traditional Medicare during the public health emergency. The public health emergency was most recently renewed effective January 16, 2022 and will remain in place through April 16, 2022. During the public health emergency, beneficiaries in any geographic area can receive telehealth services, and can receive these services in their own home, rather than needing to travel to a "distant site" (i.e., a health care setting).

Currently, policymakers are considering a variety of proposals to expand some or all of the existing flexibilities surrounding telehealth services under Medicare beyond the public health emergency, and many have expressed support for doing so. Among the telehealth-related bills that have been introduced in Congress include proposals to permanently cover some of the telehealth expansions provided during the public health emergency, expand Medicare-covered mental health services and evaluation and management services administered via telehealth, and expand the scope of providers eligible for payment for telehealth services covered by Medicare. Other bills are aimed at assessing the impact of expanded telehealth services on the quality of patient care and program spending.

B. Virtual Check-Ins.

Separate from Medicare's coverage of telehealth services, traditional Medicare covers brief, "virtual check-ins" (also called "brief communication technology-based services" - HCPCS code G2012) via telephone or captured video image, and E-visits for all beneficiaries, regardless of whether they live in a rural area. Both of these services, which were not amended during the public health emergency, are more limited in scope than a full telehealth visit. For example, virtual check-ins can only be reported by providers with an established relationship to the patient, cannot be related to a recent medical visit (within the past 7 days), and cannot lead to a medical visit in the next 24 hours (or the soonest available appointment), and payment is intended to cover only 5-10 minutes of medical discussion.

Virtual check-ins can be conducted with a broader range of communication methods, unlike Medicare telehealth visits, which require audio and visual capability for real-time communication. Doctors and certain practitioners may bill for these virtual check-in services

furnished through several communication technology modalities, such as telephone (HCPCS Code G2012). The practitioner may respond to the patient's concern by telephone, audio/video, secure text messaging, email, or use of a patient portal. In addition, separate from these virtual check-in services, captured video or images can be sent to a physician (HCPCS Code G2010).

C. E-Visits.

In all types of locations including the patient's home, and in all areas (not just rural), established Medicare patients may have non-face-to-face patient-initiated communications with their doctors without going to the doctor's office by using online patient portals. These services can only be reported when the billing practice has an established relationship with the patient. For these E-Visits, the patient must generate the initial inquiry and communications can only occur over a 7-day period. The services may be billed using CPT codes 99421-99423 and HCPCS codes G2061-G2063 as applicable.

Summary of Medicare Telemedicine Services

Type of Service	What is the service?	HCPCS/CPT Code	Patient Relationship with Provider
Medicare Telehealth Visits	A visit with a provider that uses telecommunication systems between a provider and a patient	Common telehealth services include: • 99202 - 99215 (Office or other outpatient visits) • G0425-G0427 (Telehealth consultations, emergency department or initial inpatient) • G0406-G0408 (Follow-up inpatient telehealth consultations furnished to beneficiaries in hospitals or SNFs)	For new* or established patients *To the extent the 1135 waiver requires an established relationship, HHS will not conduct audits to ensure that such a prior relationship existed for claims submitted during the public health emergency
Virtual Check-In	A brief (5-10 minutes) check in with the patient's practitioner via telephone or other telecommunications device to decide whether an office visit or other service is needed. A remote evaluation of recorded video and/or images submitted by an established patient.	• HCPCs code G2012 • HCPCs code G2010	For established patients
E-Visits	A communication between a patient and their provider through an online patient portal	• 99421 • 99422 • 99423 • G2061 • G2062 • G2063	For established patients

X. New(ish) Medicare Cards - Social Security Removal Initiative (SSNRI).

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) required CMS to remove Social Security Numbers (SSNs) from all Medicare cards by April 2019 in order to address risks of beneficiary medical identity theft. A new Medicare Beneficiary Identifier (MBI) has replaced the SSN-based Health Insurance Claim Number (HICN) on the new Medicare cards for Medicare transactions such as billing, eligibility status, and claim status.

The MBI is clearly different from the HICN.

Key	Example
SSA HICN	123-45-6789-A1
MBI	1EG4-TE5-MK73

Note in this example that the dashes are for display purposes only; they are not stored in the database nor used in file formats.

The gender and signature lines have been removed from the new Medicare cards.

The MBI the following characteristics:

(1) The name number of characters as the current HICN (11 characters), but will be visibly distinguishable from the HICN
(2) Contain uppercase alphabetic and numeric characters throughout the 11-digit identifier; positions 2, 5, 8, and 9 will always be alphabetic
(3) Occupy the same field as the HICN on transactions
(4) Be unique to each beneficiary (e.g., husband and wife will have their own NBI)
(5) Be easy to read and limit the possibility of letters being interpreted as numbers (e.g., alphabetic characters are upper case only and will exclude S, L, O, I, B, Z)
(6) Not contain any embedded intelligence or special characters

CMS began mailing the new cards in April 2018; New Jersey Medicare beneficiaries received their new cards starting in June 2018. By now, every Medicare beneficiary should have received a new Medicare card.

The Medicaid Program.

I. Background.

The Medicaid program was established in 1965 by the same federal legislation that established Medicare. Originally conceived as a medical assistance supplement for people receiving cash welfare assistance - the poorest families with dependent children, and poor aged, blind, and disabled individuals - the Medicaid program has been expanded over time by Congress and the state to address widening gaps in the private health insurance system. Unlike Medicare, Medicaid is funded jointly by the state and federal governments.

At its core, Medicaid provides health insurance to parents/caretakers and dependent children, pregnant women, and people who are aged, blind or disabled (these are the mandatory eligibility groups under federal law - known as "categorically needy"). Depending on the beneficiary's eligibility, these programs pay for hospital services, doctor visits, prescriptions, nursing home care and other healthcare needs.

Categorically needy individuals who are disqualified on the basis of income or resources above the federal eligibility limit - basically, those with too much money (although it could be as little as one dollar too much) - are classified as "medically needy." New Jersey provides coverage to the medically needy through the New Jersey FamilyCare program. FamilyCare is New Jersey's "Section 1115" waiver program, which refers to the section of the Social Security Act which permits states to pursue new approaches to operating their Medicaid programs outside of regular federal rules, but still receive federal Medicaid matching funds.

In New Jersey, the Department of Human Services, Division of Medical Assistance and Health Services (DMAHS) administers the Medicaid and NJ FamilyCare programs - DHS is the "single state agency" under federal law. Through these programs, DMAHS served 1,825,324 New Jersey residents in August 2020. Total New Jersey population is about 8.8 million, so almost 1 out of every 5 people in New Jersey is a Medicaid beneficiary.

FamilyCare/Medicaid grew significantly (by approximately 36%) beginning January 1, 2014, through expanded coverage under the Affordable Care Act (a/k/a "Obamacare"). As of October 2019, about 580,200 individuals eligible for Medicaid under the Medicaid Eligibility Expansion Groups enrolled in Medicaid. The most significant of the Medicaid Eligibility Expansion Groups are adults without dependent children (that is, single adults and childless couples). Put another way, the number of New Jersey residents enrolled in Medicaid has increased from 1 out of 7 in 2010 to 1 out of 5 today.

Due in large part to the expansion of Medicaid, the uninsured rate in New Jersey dropped from 13.2% in 2013 to just over 6% in 2020. As of October 2019, in NJ, Medicaid covers 1 in 8 adults ages 19-54, 1 in 3 children, 5 in 9 nursing home residents, 1 in 3 individuals with disabilities, and 1 in 7 Medicare beneficiaries. As of October 2019, 59% of adult Medicaid enrollees were working.

For New Jersey's population that was already eligible for Medicaid prior to 2014, the federal matching rate is only 50%, but for those newly eligible for Medicaid under the ACA's expansion, the federal government pays 90% of the cost, and that funding split will remain at that level going forward. The federal government contributes 65% to the New Jersey Children's Health Insurance Program (called, CHIP formerly known as SCHIP). (NJ is tied with nine other states for the lowest (50%) federal match rate.)

The Trump Administration vowed to repeal the ACA and replace it, but that did not come to pass. The only part of the ACA that was repealed was the individual mandate penalty, but the Supreme Court upheld the constitutionality of the Medicaid expansion. National Federal of Independent Business v. Sebelius, 567 U.S. 519 (2012)(5-4). In 2017, a New Jersey Policy Perspective report warned that 528,000 people in New Jersey (about 10% of the non-elderly population in the state at that time) could have lost their health coverage if Medicaid expansion had been eliminated. This included the 480,000 people who had gained coverage as a result of Medicaid expansion in New Jersey, but it also included additional people who were eligible for Medicaid in New Jersey prior to 2014 under Medicaid waivers that the state had negotiated with CMS. Those waivers have since expired, which didn't matter once the ACA's Medicaid expansion was in place. But if the ACA - including Medicaid expansion - had been repealed, those people wouldn't have been able to retain their Medicaid coverage.

II. Eligibility.

A. Categorically Needy. To be eligible for New Jersey Medicaid, a person must fall into one of the following categorically needy categories:

- Children age 18 and younger whose family income is at or below 355% of the federal poverty level (FPL)($8,210/month for a family of four as of January 1, 2022). Children age 18 and under who are lawfully admitted residents can be eligible, even if they have lived in this country for fewer than five years
- Parents/Caretaker Relatives with income up to 138% of the federal poverty level ($3,192/month for a family of four) must have dependent children in their household in order to be eligible under this category. (Dependent children must also be covered.) Families (includes caretakers)

with dependent children who would have qualified for Aid to Families with Dependent Children (the federal welfare program). (On July 16, 1996, the AFDC program was replaced by the Temporary Assistance to Needy Families (TANF) program. Nevertheless, eligibility for Medicaid remains linked to the pre-existing AFDC standard.) (Caretakers are typically relatives who act as parents, caring for a dependent child; they are sometimes called "kinship caregivers" or "caregiver relatives".)

- Adults age 19-64 with income up to 138% FPL ($1,563/month for a single person and $2,106/month for a couple). Immigrant adults must have legal permanent resident status in the US for at least five years in order to be eligible for NJ FamilyCare. Some immigrant adults can be eligible if they are lawfully present, regardless of when they entered the US. Examples are refugees and asylees. Immigrants age 19 and 20 who are lawfully present and have very low income ($509/month for a single person and $805/month for a family of two) can also be eligible
- People who are 65 years of age or older, or blind, or permanently disabled (who are receiving Social Security Income (SSI) or otherwise qualify for SSI under less restrictive standards)
- Low-income pregnant people and postpartum people with family income at or below 205% of the federal poverty level ($4,741/month for a family of four). Pregnant people who are lawfully admitted can be eligible even if they have lived in this country for fewer than five years.

In addition, a person must:

- Be a resident of New Jersey
- Be a US citizen or qualified alien (most immigrants who arrive after August 22, 1996 are barred from Medicaid for five years, but could be eligible for NJ FamilyCare and certain programs for pregnant people)
- Meet specific standards for financial income and resources (described below)

Eligibility for FamilyCare is determined by the NJ FamilyCare Eligibility Determining Agency (EDA). Financial eligibility is determined by the latest federal tax return which, when filed, will be electronically verified.

B. Families and Children.

1. Medicaid - NJ FamilyCare. In 1995, New Jersey Medicaid began moving Medicaid beneficiaries from a traditional fee-for-service health insurance program

into a managed care program, called NJ FamilyCare. The Affordable Care Act made dramatic changes to the Family Care program. As of January 2014, NJ Family Care refers to all Medicaid and CHIP programs (SCHIP and M-CHIP) administered by the State of New Jersey. All New Jersey Medicaid programs are included, whether they cover childless adults, parents, pregnant people, or children, and whether eligibility is based on income, disability, age or other factors.

2. FamilyCare Eligibility. Under federal law, children under age 19 qualify for Family Care (CHIP) if their family's total income before taxes is at or below 355% of the federal poverty level (FPL).

Federal law also provides that parents or caretakers of dependent children are also eligible if earned income is at or below 138% of the federal poverty level.

Applicants must be either citizens or legal immigrants who have documents that allow them to remain in the United States permanently. Parents/guardians must be legal permanent residents for at least five years in order to be eligible. (This does not apply to children or pregnant people.)

NJ FamilyCare expands eligibility of traditional Medicaid to include uninsured children whose family income is too high for them to qualify for "traditional" Medicaid, but not high enough to be able to afford private health insurance.

For example, a family of four with an annual income below 200% of the federal poverty level can get Medicaid at no cost for their children under age 19 but will incur a $5.00 to $10.00 copay. Parents cannot get coverage.

A family of four with an annual income below 300% of the federal poverty level can purchase a Medicaid plan for a premium of $151.50 per month, which covers all dependent children under age 19 years, and this coverage will have copayments ranging from $5.00 to $35.00. Parents cannot get coverage through NJ FamilyCare but can get coverage in the Affordable Care Act marketplace.

Prior to the implementation of the Affordable Care Act, families with incomes above 355% of the federal poverty level could purchase coverage for a child through NJ FamilyCare Advantage, a low-cost health insurance plan available from Horizon NJ Health. Premiums were about $160.00 per month per child. However, the Affordable Care Act supplanted the NJ FamilyCare Advantage program.

NJ FamilyCare also covers adults without dependent children, if those adults are between the ages 19 to 64 years old and have incomes up to 138% of the federal poverty level.

3. Family Care Plans. There are now four eligibility groups for Family Care - Plan A, Plan B, Plan C and Plan D, as well as NJ Family Care ABP (Alternative Benefits Plan).

Plan A Plan B Alternative Benefit Plan (ABP)	• No premium or co-pay
Plan C	• No premium for children • Co-pays of $5.00 - $10.00
Plan D	• Premiums of $42.50 - $142.50 per month, per family • Co-pays of $5.00 - $35.00

Other than the premiums and the co-pays, there are few coverage differences between the five plans. For example, all plans cover audiology services and hearing aids, but Plan D limits coverage to members under 16 years old; Plan D does not cover chiropractic services, although the other four plans do; and, Plans A and ABP cover medical day care, while Plans B, C and D do not.

Total annual premiums and co-pays under Plans C and D will exceed more than 5% of that family's year income.

4. Medicaid Special. Children under the age of 21 who do not qualify for other NJ FamilyCare programs may be eligible for the Medicaid Special Program. Family income for all family members residing in the same household is used to determine financial eligibility. For example, children 19 or 20 years of age, who have "aged out" of NJ FamilyCare may be eligible if their family has earned income at or below 138% of the federal poverty level.

C. Aged, Blind, and Disabled.

1. New Jersey Care (Special Medical Program for the Aged, Blind, and Disabled). To qualify for this program, an individual must:

- Be 65 years of age or older, and/or
- Be determined to be blind or disabled by either the Social Security Administration or by the NJ Division of Medical Assistance and Health Services
- Meet the general requirements for NJ Medicaid (resident and US citizen or qualified alien)

2. Medically Needy Section of Medicaid for the Aged, Blind, or Permanently Disabled. This special program provides limited health coverage to aged, blind or disabled people who do not qualify for traditional New Jersey Medicaid because their income or financial resources are too high. It includes a "spend down" provision that allows documented medical expenses to be used to reduce monthly income to meet eligibility limits.

   People who qualify for this medically needy section of New Jersey Medicaid are entitled to most Medicaid services. Exceptions include such things as inpatient hospital care, prescriptions, podiatry and chiropractic services. Long-term care services are covered.

3. Long-term Care for the Aged, Blind, and Permanently Disabled. Applicants for this program are considered on an individual basis. Once eligibility is established, full Medicaid coverage is provided. However, the individual's income must be applied to offset the cost of the long-term care. For purposes of this program, approved facilities include:

   - Acute care general hospitals
   - Nursing facilities
   - Facilities to assist the developmentally disabled
   - Psychiatric hospitals for persons under age 21 and over age 65

   Nationally, in 2019, Medicaid financed 43% of all long-term care spending, and more than 6 of every 10 nursing home residents are covered by Medicaid. In fact, almost 67% of all Medicaid spending in the US is attributable to the elderly and persons with disabilities, even though they represent less than 25% of all enrollees.

4. Waiver Programs for Receiving Services in the Community. In certain circumstances, the types of services offered in long term care can be provided in the community by means of a waiver program. Such

programs allow beneficiaries to remain in community settings, such as their own home or an assisted living facility, while receiving certain Medicaid services.

D. Pregnant People.

NJ FamilyCare programs will cover pregnant people with incomes at or below 205% of the federal poverty level. This coverage extends to women during pregnancy and for 60 days following delivery or the date on which the pregnancy ends.

A child born to an eligible Medicaid mother is eligible for NJ FamilyCare for one year regardless of changes in the family's income.

E. Qualified Medicare Beneficiaries.

Medicaid pays Medicare premiums, deductibles and coinsurance for Qualified Medicare Beneficiaries (QMBs) or "dually eligible" beneficiaries. The QMB program provides Medicare coverage of Part A and Part B premiums and cost sharing to low-income Medicare beneficiaries. There are two categories of QMBs:

1. Beneficiaries whose income is at or below 100% of the federal poverty level and whose resources are at or below twice the standard allowed under SSI.

2. Beneficiaries with income greater than 100% but less than 135% of the federal poverty level.

No Original Medicare or Medicare Advantage providers or suppliers can charge QMBs for any Medicare Part A and Part B cost sharing for covered services. Medicaid is supposed to pay for all deductibles and coinsurance amounts, but as a practical matter, since Medicaid rates are lower than Medicare rates, and since Medicaid adjudicates its claims at its lower rate, provider usually don't receive any more payments above the amount paid by Medicare.

III. Managed Care.

In New Jersey, almost all Medicaid beneficiaries are enrolled in managed care. The Division of Medical Assistance and Health Services has been providing mandatory managed care services for the AFDC/TANF (Aid to Families with Dependent Children and Temporary Assistance for Needy Families a/k/a WorkFirstNJ) since 1995 and to the NJ FamilyCare

beneficiaries since 1998, through the New Jersey Care 2000 program. On October 1, 2000, the program was expanded to move the Aged, Blind and Disabled (ABD) populations into mandatory managed care. The new, expanded program, New Jersey Care 2000, requires all non-dually eligible (Medicaid, no Medicare) ABD clients, and clients enrolled in the Division of Disability Services Community Care Waiver, to enroll in an HMO to receive Medicaid benefits.

There are currently five HMOs providing Medicaid managed care services in New Jersey:

- Aetna Better Health of New Jersey
- Amerigroup New Jersey, Inc.
- Horizon NJ Health
- UnitedHealthcare Community Plan
- WellCare (acquired Healthfirst NJ effective July 1, 2014)

IV. Physician Enrollment/Participation and Non-Billing Provider.

A. Physician Enrollment/Participation. Physicians need to enroll in the Medicaid program and once enrolled, they can sign participation agreements with each HMO. Providers enroll online at the New Jersey Medicaid Management Information System website, which is managed by Gainwell Technologies (which acquired Molina Medicaid Solutions).

B. Non-Billing Provider. The Patient Protection and Affordable Care Act of 2010 (ACA) requires that all healthcare professionals who provide, refer, order, operate, or prescribe any type of service for a New Jersey Charity Care (NJCC)/NJ FamilyCare (NJFC)/Medicaid fee-for-service (FFS) beneficiary enroll in the NJFC/Medicaid program by no later than January 1, 2013 as a "non-billing" provider, unless already enrolled in the NJFC/Medicaid program as a "billing" provider.

A "non-billing" provider is a healthcare professional (i.e., physician or advance practice nurse) who refers, orders, operates, prescribes, or attends to the medical needs of a NJCC/NJFC/Medicaid FFS beneficiary. A "non-billing" provider is a healthcare professional who may prescribe a NJCC/NJFC/Medicaid-covered service, such as a medication; complete a physician order for a beneficiary's care; act as a referral source for a beneficiary or otherwise attend to a beneficiary's healthcare needs. Those professionals who only enroll in the NJFC/Medicaid as a "non-billing" provider are not eligible to receive payments from the NJCC/NJFC/Medicaid program. However, the enrollment of a professional who refers, orders, operates, prescribes, or attends to the medical needs of a FFS NJCC/NJFC/Medicaid beneficiary is required in order for a covered service to be paid to a "billing" provider by the NJFC/Medicaid program or the

NJ Charity Care fund.

For example, the physician who prescribes medication must be enrolled as a "non-billing" provider or already be enrolled as a "billing" provider in order for a pharmacy to receive payment for the medication dispensed.

Selected FAQs from the DMAHS Newsletter (December 2021):

ii. **Is a "non-billing" provider eligible to receive NJCC/NJFC/Medicaid FFS payments?**

A "non-billing" provider is not eligible to receive NJCC/NJFC/Medicaid FFS payments. Providers requesting payments from NJCC/NJFC/Medicaid FFS Programs must enroll as a "billing" provider.

10. **Are all attending physicians practicing in a hospital setting required to enroll in NJCC and/or the NJFC/Medicaid FFS program as a "non-billing" provider?**

Yes, all attending physicians providing healthcare services to NJCC/NJFC/Medicaid FFS beneficiaries in a hospital setting must enroll as a "non-billing" provider in the NJFC/ Medicaid FFS program.

12. **Is my practice obligated to provide medical care to a NJFC/Medicaid FFS beneficiary if I enroll as a "non-billing" provider?**

Your practice is not obligated to provide medical care to a NJFC/Medicaid FFS beneficiary after enrolling in the NJFC/Medicaid program as a "non-billing" provider. Enrolling as a "non-billing" provider only offers a practitioner the opportunity to refer, order, operate, prescribe or in some way attend to the medical needs of a NJFC/Medicaid FFS beneficiary without anticipating payment from the NJFC/Medicaid program.

13. **If a physician does not enroll as a "non-billing" provider, will the hospital be paid by NJCC or the NJFC/Medicaid program for inpatient or outpatient services provided by the hospital?**

If a physician does not enroll as a "non-billing" provider, the hospital will not be paid by NJCC and/or the NJFC/Medicaid FFS program for inpatient or outpatient services referred, ordered or prescribed by that attending physician.

V. Children's Health Insurance Program.

Children's Health Insurance Program - generally known as CHIP - is a program in which the U.S. Department of Health and Human Services provides matching funds to the State of New Jersey for fund uninsured children in families with incomes that are modest but too high to qualify for Medicaid; it is codified as Title XXI of the Social Security Act. New Jersey does not operate an independent CHIP program, but instead uses CHIP funds to expand the FamilyCare program.

VI. Medicaid Services.

A. Mandatory Services. Mandatory services provided for all New Jersey Medicaid clients:

- Inpatient and outpatient hospital treatment
- Laboratory tests and x-rays
- Early and Periodic Screening, Diagnosis and Treatment (EPSDT)
- Home health care
- Physician services
- Nurse-midwife services
- Assistance with family planning and necessary supplies
- Nursing facilities for people over age 21 years

B. Optional Services. Optional services provided to New Jersey Medicaid clients enrolled in specific programs:

- Treatment in residential treatment centers
- Optical appliances
- Dental care
- Optometry services
- Chiropractic services
- Psychologist
- Podiatrist
- Prosthetics and orthotics
- Drugs necessary during long term care
- Drugs at retail cost
- Durable medical equipment
- Hearing aid services
- Hospice care

- Transportation
- Personal care services
- Licensed practitioner services
- Private duty nursing
- Services in a clinic
- Physical, occupational and speech therapy
- Inpatient psychiatric care for individuals under age 21 and over age 65
- Intermediate care facilities for the mentally retarded

C. Early and Periodic Screening, Diagnosis, and Treatment (EPSDT). The pediatric Medicaid benefit, known as Early and Periodic Screening, Diagnosis, and Treatment encompasses a comprehensive array of health services. EPSDT is a mandatory benefit that entitles Medicaid enrollees under age 21 to all services authorized by federal Medicaid law, including services considered optional for other populations (e.g., dental care) and often not covered by private health insurance. In addition to screening, preventive, and early intervention services, EPSDT covers diagnostic services and treatment necessary to correct or ameliorate children's acute and chronic physical and mental health conditions. EPSDT covers services that are particularly important, on an ongoing basis, for children with disabilities, such as physical therapy, personal care, and durable medical equipment. Private health insurance often excludes or limits these services.

The concept of medical necessity in EPSDT is expansive, consistent with the emphasis in Medicaid on promoting children's health development and maximizing their health function. Accordingly, service limits that states may impose on adults, such as a limit on physical therapy sessions, or a maximum number of prescriptions per month, cannot be applied to children. As a model of uniform, comprehensive benefits that apply to a population nationally, EPSDT is unique in Medicaid and the broader insurance market.

D. Reimbursement. Medicaid cost per enrollee in New Jersey is the highest in the nation - approximately $9,560 per person per year in 2014 (the most recent statistics available). At the same time, though, New Jersey Medicaid reimbursement rates are among the lowest in the county. As a result, New Jersey has the lowest percentage of doctors who accept Medicaid patients. In a study published in May 2017, the Kaiser Family Foundation found that 39% of NJ doctors did not take new Medicaid patients, which was the lowest participation rate in the country and well below the national average of 70%.

In 2013, the ACA temporarily boosted Medicaid payment rates to Medicare levels for primary care physicians. It was designed to be a two-year program, but funds did not

start flowing until early 2014. In New Jersey, for 146 primary care services, Medicaid reimbursement increased an average of 109%. By way of example, in New Jersey, in 2014, Medicare reimbursed a 99213 (E&M level 3, established patient) at $81.33, and Medicaid also reimbursed at that amount. However, the ACA increase for primary care services expired on January 1, 2015 and Medicaid reimbursement rates to New Jersey providers declined by 53%. (For reference, in 2016, Medicare reimbursed a 99213 at $81.65 and Medicaid paid $40.88. In 2020, Medicaid reimbursement declined to $39.85 for a specialist and $33.67 for a non-specialist.) Although the program was designed to boost participation by physicians in the Medicaid program, news reports at the time indicated that the increased payments did not attract additional physicians to participate in Medicaid.

E. Telemedicine. On July 21, 2017, New Jersey enacted broad-based telemedicine legislation which includes a requirement that the Medicaid and New Jersey FamilyCare programs cover and reimburse telemedicine services.

With regard to Medicaid and Medicaid managed care, the law states that the State Medicaid Program and NJ FamilyCare Program "shall provide coverage and payment for health care services delivered to a benefits recipient through telemedicine or telehealth, on the same basis as, and at a provider reimbursement rate that does not exceed the provider reimbursement rate that is applicable, when the services are delivered through in-person contact and consultation in New Jersey."

Reimbursement payments may be provided either to the individual practitioner who delivered the reimbursable services, or to the agency, facility, or organization that employs the individual practitioner who delivered the reimbursable services, as appropriate.

The programs may limit coverage to services that are delivered by participating health care providers, but may not charge any deductible, copayment, or coinsurance for a health care service, delivered through telemedicine or telehealth, in an amount that exceeds the deductible, copayment, or coinsurance amount that is applicable to an in-person consultation.

F. Network Adequacy of Pediatric Providers. On November 8, 2021, Governor Murphy signed S3000 (P.L.2021, c.276) which amended the definition of network adequacy of pediatric providers for the state's managed Medicaid plans to essentially allow children to seek care from out-of-state specialty hospitals, like Children's Hospital of Philadelphia, as of right, without seeking a single case agreement between the patient and the MCO. N.J.S.A. 26:2S-1 et seq.

- S3000 requires Medicaid MCOs to include the full range of pediatric services in-network, which means no single case agreement is needed for families to access care; just the normal referral process establishing a need for the care;

- Prior to S3000, the law required plans to have a specialist within 45 miles or 60 minutes of travel time for all families. S3000 amended the law to require that pediatric specialists would need to be available within 15 miles or 30 minutes for those in urban counties and 40 miles or 60 minutes for those in more rural areas. It sets a special metric for pediatric oncologists and specialists who treat behavioral and developmental issues of 10 miles or 20 minutes in urban areas and 30 miles or 45 minutes for those in rural counties;

- No out-of-state pediatric specialty hospital shall be denied the right to participate in a MCO network under the same terms and conditions currently applicable to all other contracting providers, provided the pediatric specialty hospital is willing to accept 125 percent of its home state Medicaid fee-for-service rate and accepts the terms and conditions of the contract;

- No out-of-state or in-state pediatric specialty provider shall be denied the right to participate in a MCO network under the same terms and conditions currently applicable to all other contracting providers, provided the out-of-state or in-state pediatric specialty provider is willing to accept 100 percent of the State Medicaid fee-for-service rate and accepts the terms and conditions of the contract.

- S3000 establishes a 30-day grievance process through which families or providers can raise concerns that the required care, within the required time and distance, is not being provided as required by the legislation;

- S3000 creates a process under which Medicaid MCOs can establish that, despite a good faith effort, the care cannot be provided in-network and/or within the established time-and-distance requirements, allowing the Medicaid MCO to rely on a single case agreement, or similar arrangement, to approve the care in a timely fashion similar to that of an in-network provider;

- S3000 require the state to establish an oversight process for ensuring that Medicaid managed care organizations follow the requirements established by the legislation; and

- S3000 does not permit that a provider or family insist on care with a particular provider unless that care is not otherwise available within the limits defined in the legislation.

VII. Third Party Liability in the Medicaid Program.

A. Medicaid Third Party Liability. By law, the Medicaid program is the payer of last resort. If another insurer or program has the responsibility to pay for medical costs incurred by a Medicaid-eligible individual, that entity is generally required to pay all or part of the cost of the claim prior to Medicaid making any payment. This is known as "third party liability." Third parties that may be liable to pay for services include private health insurance, Medicare, employer-sponsored health insurance, settlements from a liability insurer, workers' compensation, and long-term care insurance.

In general, if a state has determined that a potentially liable third party exists, it must attempt to ensure that the provider bills the third party before sending the claim to Medicaid. This is known as "cost avoidance." Whenever a state has paid claims and subsequently discovers the existence of a liable third party, it must attempt to recover the money from the liable third party. This is known as "pay and chase."

B. Recoveries from Estates of Deceased Medicaid Clients and Former Medicaid Clients. Under federal and New Jersey law, the Division of Medical Assistance and Health Services is required to recover funds from the estates of certain deceased Medicaid clients or former clients for all payments provided through the Medicaid program for services received on or after age 55.

Evaluation and Management Services.

I. Background.

Evaluation and Management (E/M) coding is the process by which physician-patient encounters are translated into five-digit CPT codes to facilitate billing. CPT stands for "current procedural terminology," which is a classification system developed by the American Medical Association (AMA). CPT codes are numeric codes which are submitted to insurers for payment. Every billable procedure has its own individual CPT code. Medicare and Medicaid use a variation of the CPT codes, called Healthcare Common Procedure Coding Systems (HCPCS), which is virtually identical to the CPT codes.

The CPT codes which describe physician-patient encounters are often referred to as "E/M codes." There are different E/M codes for different types of encounters such as office visits or hospital visits. Within each type of encounter, there are different levels of care. Until January 1, 2021, there were five levels of E/M care for new patients and five levels of E/M care for established patients, but on January 1, 2021, the AMA eliminated the lowest level of care (previously called a "level 1" office visit) for new patients. For example, the 99214 code is used to charge for an office visit with an established patient. The 99214 code is often called a "level 4" office visit because the code ends in a "4" and also because it is the fourth "level of care" for that type of visit (with the 99215 being the fifth and highest level of care).

For most primary care physicians, E/M codes represent the majority of patient care encounters; as such, it is useful to have a fundamental understanding of E/M codes.

New E/M Codes Effective January 1, 2021.

Effective January 1, 2021, the AMA changed the definition of the time element associated with codes 99202-99215 from typical face-to-face time to total time spent on the day of the encounter, as well as changing the amount of time associated with each code.

These changes included:

- Eliminating history and physical exam as elements for code selection. (While significant to both visit time and medical decision-making, these elements alone should not determine a visit's code level.)
- Allowing physicians to choose whether their documentation is based on medical decision-making (MDM) or total time. (This builds on the movement to better recognize the work involved in non-face-to-face services like care coordination.)

- Modifying MDM criteria to move away from simply adding up tasks to focus on tasks that affect the management of a patient's condition.

The revised coding guidelines for outpatient evaluation and management (E/M) services represent the first major overhaul of E/M reporting in more than 25 years. These changes have significant potential to give doctors more time to spend with patients by freeing them from clinically irrelevant administrative burdens that led to time-wasting note bloat and box checking.

What hasn't changed is that medical necessity for the level of service must be identifiable within the documentation. Although documentation of history and physical examination will still need to be medically appropriate, the amount of history or number of elements examined and documented will not factor into the scoring used to determine the overall E/M level of service. Instead, the basis for code selection will be the level of MDM performed or the total time spent performing the service on the day of the encounter.

Medical decision-making or time will be the determining factor in level-of-service selection. But the new definition of time is different – including the total face-to-face and non-face-to-face time spent involved in patient care activities including:

1. Preparing to see the patient (review of test results)
2. Obtaining and/or reviewing separately obtained history
3. Performing a medically appropriate examination and/or evaluation
4. Counseling and educating the patient/family/caregiver
5. Ordering medications, tests, or procedures
6. Referring and communicating with other healthcare professionals (when not separately reported)
7. Documenting clinical information in the electronic or other health records
8. Independently interpreting results (not separately reported) and communicating results to the patient/family/caregiver
9. Care coordination (not separately reported)

Changes to medical decision-making resemble a reconfiguration of the three MDM sections into the format of the Risk Table, with some notable improvements:

1. Each unique test, order, or document counts – meaning that instead of multiple lab or radiology or medical tests simply counting as one item in that category, each unique test counts toward the overall volume, for both reviewing and ordering.
2. The decision for hospitalization has been acknowledged in the risk category.
3. Definitions have been provided for the elements listed in the revised MDM table for greater clarity.

II. Office Visits - New Patients vs. Established Patients.

Evaluation and Management Code (New Patients)	Time	Average Time
99202	20 minutes	15 - 29 minutes
99203	30 minutes	30 - 44 minutes
99204	45 minutes	45 - 59 minutes
99205	60 minutes	60 - 74 minutes

Evaluation and Management Code (Established Patients)		
99211*		
99212	10 minutes	10 - 19 minutes
99213	15 minutes	20 - 29 minutes
99214	25 minutes	30 - 39 minutes
99215	40 minutes	40 - 54 minutes

*99211: Level-1 established patient E/M code 99211 is still available, but the 2021 code descriptor does not include the time reference that was in the 2020 descriptor.

A. Documentation of Time Includes:

1. Face to Face.

- Performing a medically appropriate examination and/or evaluation
- Counseling and educating the patient/family/caregiver

2. Non-Face to Face.

- Preparing to see the patient
- Obtaining and/or reviewing separately obtained history
- Ordering medications, tests or procedures
- Referring and communicating with other health care professionals (when not reported separately)
- Documenting clinical information in the electronic or other health record
- Independently interpreting results (not separately reported) and communicating results to the patient/family/caregiver
- Care coordination (not separately reported)

B. Medical Decision-making Components

- Number and complexity of problems addressed
- Amount and/or complexity of data reviewed and analyzed
- Risk of complications and/or morbidity or mortality

- Data will be divided into three categories:
    - Category 1: test, documents, orders, and review of prior external note(s) from each unique source or independent historian(s) - each unique test, order, or document is counted to meet a threshold number (not reported separately)
    - Category 2: independent interpretation of tests not reported separately
    - Category 3: discussion of management or test interpretation with external physician/other qualified health care provider/appropriate source (not reported separately)

C. Understanding MDM Data Components

- As per the AMA, if you bill for the test, do not count it as ordered or reviewed
- The actual performance and/or interpretation of diagnostic tests/studies during a patient encounter are not included in determining the levels of E/M services when reported separately
- No MDM credit for test that are separately reported/billed by the physician/medical practice

Number and Complexity of Problems Addressed	Amount and/or Complexity of Data to be Reviewed and Analyzed	Risk of Complications and/or Morbidity or Mortality of Patient Management	MDM	Code Level
• 1 self-limited or minor problem [for example, cold, insect bite, tinea corporis (ringworm)]	Minimal or none [Diagnostic Procedures Ordered: laboratory tests requiring venipuncture, chest x-rays, EKG/EEG, urinalysis, ultrasound (ex. Echocardiography, KOH prep (diagnoses ringworm)]	Minimal risk of morbidity from additional diagnostic testing or treatment [Management Options Selected: rest, gargles, elastic bandages, superficial dressings]	SF	99202 99212
• 2 or more self-limited or minor problems OR • 1 stable chronic illness [for example, well controlled hypertension, non-insulin dependent diabetes, cataract, BPH (benign prostatic hyperplasia)] OR • 1 acute, uncomplicated illness or injury [for example, cystitis, allergic rhinitis, simple sprain]	(Must meet the requirements of at least 1 of the 2 categories) Category 1: Tests and Documents Any combination of 2 of the following: • Review of prior external note(s) from each unique source • Review of the result(s) of each unique test Or Category 2: Assessment requiring an independent historian(s) [Diagnostic Procedures Ordered: physiologic test not under stress (for example, pulmonary function tests), non-cardiovascular imaging studies with contrast (for example, barium enema), superficial needle biopsies, clinical laboratory tests requiring arterial puncture, skin biopsies]	Low risk of morbidity from additional diagnostic testing or treatment [Management Options Selected: OTC drugs, minor surgery with no identified risk factors, PT, OT, IV fluids w/o additives]	Low	99203 99213

Number and Complexity of Problems Addressed	Amount and/or Complexity of Data to be Reviewed and Analyzed	Risk of Complications and/or Morbidity or Mortality of Patient Management	MDM	Code Level
• 1 or more chronic illnesses with mild exacerbation, progression, or side effects of treatment; OR • 2 or more stable chronic illnesses; OR • 1 undiagnosed new problem with uncertain prognosis [for example, breast lump]; OR • 1 acute illness with systemic symptoms [for example, pyelonephritis (UTI), pneumonitis (lung inflammation), colitis] OR • 1 acute complicated injury [for example, head injury with brief loss of consciousness]	(Must meet the criteria of at least 1 of the 3 categories) Category 1: Tests, Documents, or independent historian(s) Any combination of 3 of the following: • Review of prior external note(s) from each unique source • Review of the result(s) of each unique test • Ordering of each unique test • Assessment requiring an independent historian(s) OR Category 2: Independent interpretation of tests; Independent interpretation of a test performed by another physician/qualified health care professional (not separately reported) OR Category 3: Discussion of management or test interpretation; Discussion of management or test interpretation with external physician/ other qualified health care professional/ appropriate source (not separately reported) [Diagnostic Procedures Ordered: physiologic tests under stress (for example, cardiac stress test, fetal contraction stress test), diagnostic endoscopies with no identified risk factors,	Moderate Examples only: • Prescription drug management • Decision regarding minor surgery with identified patient or procedure risk factors; • Decision regarding elective major surgery without identified patient or procedure risk factors • Diagnosis or treatment significantly limited by social determinates of health [Management Options Selected: minor surgery with identified risk factors, elective major surgery (open, percutaneous or endoscopic) with no identified risk factors, prescription drug management, therapeutic nuclear medicine, IV fluids with additives, closed treatment of fracture or dislocation without manipulation]	Mod	99204 99214

Number and Complexity of Problems Addressed	Amount and/or Complexity of Data to be Reviewed and Analyzed	Risk of Complications and/or Morbidity or Mortality of Patient Management	MDM	Code Level
	deep needle or incisional biopsy, cardiovascular imaging studies with contrast and no identified risk factors (for example, arteriogram, cardiac catheterization), obtain fluid from body cavity (for example, lumbar puncture, thoracentesis, culdocentesis)]			
• 1 or more chronic illnesses with severe exacerbation, progression, or side effects of treatment OR • acute or chronic illness or injury that pose a threat to life or bodily function [for example, multiple trauma, acute MI, pulmonary embolus, severe respiratory distress, progressive rheumatoid arthritis, psychiatric illness with potential threat to self or others, peritonitis, acute renal failure] OR • an abrupt change in neurologic status [for example, seizure, TIA	Category 1: Tests, Documents, or independent historian(s) Any combination of 3 of the following: • Review of prior external note(s) from each unique source • Review of the result(s) of each unique test • Ordering of each unique test • Assessment requiring an independent historian(s) OR Category 2: Independent interpretation of tests; Independent interpretation of a test performed by another physician/qualified health care professional (not separately reported) OR Category 3: Discussion of management or test interpretation; Discussion of management or test interpretation with external physician/ other qualified health care professional/ appropriate source (not separately reported)	High Examples only: • Drug therapy requiring intensive monitoring for toxicity • Decision regarding elective major surgery with identified patient or procedure risk factors • Decision regarding emergency major surgery • Decision regarding hospitalization • Decision not to resuscitate or to de-escalate care because of poor prognosis [Management Options Selected: elective major surgery (open, percutaneous or endoscopic) with identified risk factors, emergency major surgery (open, percutaneous or endoscopic), parenteral controlled substances, drug therapy requiring intensive monitoring for toxicity, decision not to resuscitate or to	High	99205 99215

Number and Complexity of Problems Addressed	Amount and/or Complexity of Data to be Reviewed and Analyzed	Risk of Complications and/or Morbidity or Mortality of Patient Management	MDM	Code Level
(similar to a stroke), weakness, sensory loss]	[Diagnostic Procedures Ordered: cardiovascular imaging studies with contrast with identified risk factors, cardiac electrophysiological tests, diagnostic endoscopies with identified risk factors, discography]	de-escalate care because of poor prognosis]		

D. What is considered a "Problem"? A problem is a disease, condition, illness, injury, symptom, sign, finding, complaint, or other matter addressed at the encounter, with or without a diagnosis being established at the time of the encounter.

E. What is considered a "Problem Addressed"? A problem is addressed or managed when it is evaluated or treated at the encounter by the physician or other qualified health care professional reporting the service.

- This includes consideration of further testing or treatment that may not be elected by virtue of risk/benefit analysis or patient/parent/guardian/surrogate choice
- Notation in the patient's medical record that another professional is managing the problem without additional assessment or care coordination documented does not qualify as being "addressed" or managed by the physician or other qualified health care professional reporting the service
- Referral without evaluation (by history, exam, or diagnostic study[ies]) or consideration of treatment does not qualify as being addressed or managed by the physician or other qualified health care professional reporting the service

F. Medical Necessity. The medical necessity of a service is the overarching criterion for payment in addition to the individual requirements for a CPT code. It would not be medically necessary or appropriate to bill a higher level of E/M service when a lower level of service is warranted. The volume of documentation is not the primary influence upon which a specific level of service is billed – the condition of the patient must warrant the level of service and those services must be provided (as well as properly documented).

III. Basic Principles of Medical Record Documentation.

Each patient care encounter is a unique procedure which requires specific documentation. There is no specific format required for documenting the components of an E&M service, but there are some basic principles and common elements:

1. The medical record should be complete and legible.
2. The documentation of each patient encounter should include:
    a. The patient's name and appropriate demographic information
    b. The chief complaint and/or reason for the encounter and relevant history, physical examination findings and prior diagnostic results
    c. Assessment, clinical impression or diagnosis
    d. Plan for care, and

e. Date and a verifiable identity of the health care professional who provided the services

3. If not specifically documented, the rationale for ordering diagnostic and other ancillary services should be able to be easily inferred.
4. To the greatest extent possible, past and present diagnoses and conditions should be accessible to the treating and/or consulting physician. This should include those diagnoses and conditions from the prenatal and intrapartum period that affect newborns.
5. Appropriate health risk factors, including allergies, should be identified.
6. The patient's progress, response to and changes in treatment, planned follow-up care, and instructions and diagnosis should be documented.
7. The CPT and International Classification of Diseases (ICD) codes reported on the claim (typically, submitted electronically; occasionally submitted using a CMS form 1500) should be supported by the documentation in the medical record.
8. Any addendum to the medical record should be dated the day the information is added to the medical record and not dated for the date the service was provided.
9. Documentation should be timely. A service should be documented during the visit, or soon after it is provided, in order to maintain an accurate medical record.
10. The confidentiality of the medical record should be fully maintained, consistent with the requirements of medical ethics and law (Health Insurance Portability and Accountability Act of 1996 - HIPAA).

Since January 1, 2021, practitioners should be documenting actual time and activities performed. For example, "I spent 45 minutes caring for this patient today, reviewing labs, records from another facility, seeing the patient, documenting in the record and arranging for a sleep study."

The development of Electronic Health Records (EHR), which are based on a template, should lead to more comprehensive documentation, but that is not necessarily the case. Medical records audits have found that many practitioners are employing macros which pre-populate the EHR with standard - and often inapplicable - information. As EHRs are shared among practitioners, more inaccurate medical records will come to light. This only intensifies the need for practitioners to document each patient encounter with care.

IV. Consultations.

According to the AMA, a "consultation" is defined as a type of service that:

- Is provided by a physician;
- Requires an opinion or advice regarding the evaluation and management of a specific problem; and,
- Is requested by another physician or other appropriate source.

The consultant's opinion and any services that are ordered or performed must be documented in the patient's medical record and communicated by written report to the requesting physician. Consultations are performed by specialists and reports are submitted to the referring primary care physician. Consultations are billed using CPT codes 99241-99245 and 99251-99255.

In the past, consultation codes reimbursed at a higher rate than E/M codes. As such, specialists loved to bill for consultations, but Medicare determined that many specialists were not preparing and providing written reports. As a result, on January 1, 2010, Medicare eliminated reimbursement for consultation codes. Instead, physicians are to report consultations using E/M codes.

The elimination of the consultation codes did not decrease Medicare payments. In place of the consultation codes, CMS increased the work relative value units (wRVUs) for new and established office visits and incorporated the increased use of these visits into the practice expense (PE) and malpractice calculations.

Although consultation codes have been eliminated, CMS encourages physicians to continue to follow the medical practice convention of documenting referral requests, referral acceptances, and communication of findings after evaluation by the specialist to the referring physician.

V. E/M Service Documentation Provided by Students.

Effective January 1, 2018, Medicare allows a teaching physician to verify in the medical record any student documentation of components of E/M services, rather than re-documenting the work. Students may document services in the medical record; however, the teaching physician must verify in the medical record all student documentation of findings, including history, physical exam and/or medical decision making. The teaching physician must personally perform (or re-perform) the physical exam and medical decision-making activities of the E/M service being billed but may verify any student documentation of them in the medical record, rather than re-documenting this work.

VI. Shared or Split Services.

A. *Synopsis.*

- Shared or split services are Evaluation and Management (E/M) services performed jointly between a physician and a non-physician practitioner (NPP), in the same group, in a facility setting.

- Services may include both face-to-face and non-face-to-face activities.

- Services billed using the physician's NPI are paid at a higher rate than those billed by a non-physician practitioner.

- CMS states that the service should be reported by the clinician who performs a substantive portion of the visit. 2022 is a transitional year, allowing either time or a key component to determine the substantive portion.

- New HCPCS modifier commencing 1/1/2022 is "FS" for Split (or shared) Evaluation and Management service.

B. *Services that can be reported as shared or split.*

E/M services may be billed as shared or split services when provided in a facility setting. Prior to 2022, they could be provided in an office setting if they also met the requirements for incident-to billing. CMS is no longer allowing shared services in an office setting, although incident-to services in the office are still allowed.

Specifically, office and other outpatient codes 99202–99215 can be billed as shared services in a facility setting, that is, an outpatient department. Inpatient hospital services, observation services and emergency department visits can also be billed as shared services. Beginning in 2022, nursing facility services can be billed as shared services, except for the mandated visits which must be performed by a physician in the nursing facilities participation of care rules. Beginning in 2022, critical care services jointly performed by a physician and a non-physician practitioner can be billed as shared or split services.

CMS's Final Rule uses the term "nonfacility" and "noninstutional" to describe place of service. However, it is really helpful to consider CPT place of service codes. Office and other outpatient services (99202–99215) reported in place of service 11 office may **not** be reported as shared services. Office and other outpatient codes in place of service 19 or 22, outpatient hospital, may be reported as shared services.

C. *The substantive portion.*

In the Final Rule, CMS notes that withdrawn manual sections contained different definitions of the requirements. "For example, one section defined substantive portion as any face-to-face portion of the visit, while another section defined it as one of the three key components of an E/M service - either the history of the present illness (HPI), physical exam, and/or MDM." In this section, the rule states "Given recent changes in the CPT E/M Guidelines,

HPI [history of present illness] and physical exam are no longer necessarily included in all E/M visits . . . ."

D. *CMS is setting different definitions of substantive for 2022 and 2023.*

CMS is requiring that the shared visit be reported under the provider number of the physician or non-physician practitioner who has performed a substantive portion of the visit. If the physician is not performing a substantive portion of the service, then CMS believes the rate of payment should be at the 85% rate, paid for NPP services.

For 2022, a transitional year, CMS is defining a substantive portion of the service as the practitioner who performed more than 50% of the time of the visit, or the practitioner who performed and documented in its entirety either the history, exam, or medical decision-making portion of the note. Because these office and other outpatient visit codes do not have specific history and exam requirements, it makes sense to use MDM as the component for 99202–99215, if not using time. "We are clarifying that when one of the three key components is used as the substantive portion in 2022, the practitioner who bills the visit must perform that component in its entirety in order to bill. For example, if history is used as the substantive portion and both practitioners take part of the history, the billing practitioner must perform the level of history required to select the visit level billed."

Office visits in an outpatient department use either time or MDM. If the physician performs and documents all of the assessment and plan, then consider that the substantive portion. If the physician spends more than 50% of the time, consider that the substantive portion. If using time as the substantive portion, each clinician should document the time they spent. If neither of those is true, bill under the NPP provider number.

For emergency department visits, you must select the level of service based on the three key components. But you can determine the substantive portion either by the practitioner who spent to the most time, or the key components. If the physician documents in its entirety either the history, exam or MDM, bill under the physician's NPI.

For inpatient, observation and nursing facility services, if billing under the physician's NPI, use either time or one of the key components to support the substantive portion. Either the physician must have spent greater than 50% of the unit time, or the physician must have documented one of the key components in its entirety. If using time, both clinicians will need to document their time, so that it is clear which practitioner spent more than 50%. Use the current activities listed in CPT.

In 2023 CMS will require that shared services be reported by the provider who provides more than half of the time of the service. CMS is proposing that all of the activities that are listed in the current CPT book as activities that can be included in the time of the visit can be counted in this calculation.

E. *Documentation of shared services.*

If billing shared services, the documentation must identify the two individuals who performed the service. CMS points out that in prior years, it finalized a rule that "any individual who is authorized under Medicare law to furnish and bill for their professional services, whether or not they are acting in a teaching role, may review and verify (sign and date) the medical record for the services they bill, rather than re-document notes in the medical record . . . ."

CMS states that it may be helpful for each individual to document their own participation in the record, in order to determine the substantive time. CMS further states that the record must identify the two individuals who performed the services, and "[t]he individual who performed the substantive portion (and therefore, bills the visit) must sign and date the medical record."

Glossary of Medicare/Medicaid Terminology and List of Abbreviations.

A glossary of Medicare/Medicaid terminology is online at: https://www.healthcare.gov/glossary/

Term	Meaning
ACI	Advancing Care Information
AHP	Association Health Plan
APC	Ambulatory Payment Classifications. APCs are CMS' method of paying facilities for outpatient services covered by Medicare
ASC	Ambulatory Surgery Center
BAA	Business Associate Agreement. Covered entities and their business associates must execute agreements whereby the business associate agrees to comply with certain HIPAA Privacy and Security Rule provisions affecting protected health information ("PHI").
Big Data	Originally referring to data sets that are so voluminous and complex that traditional data processing application software are inadequate to deal with them, more recently Big Data refers to the use of predictive analytics, user behavior analytics, or certain other advanced data analytics methods that extract value from data, without reference to the size of a particular data set.
BPCI	Bundled Payment for Care Improvement
BPCI-Advanced	Bundled Payment for Care Improvement-Advanced
Business Associate	A "business associate" under HIPAA is a person or entity that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, a covered entity. A member of the covered entity's workforce is not a business associate.
CAH	Critical Access Hospital. A CAH is a designation given to eligible rural hospitals by CMS. The CAH designation is designed to reduce the financial vulnerability of rural hospitals and improve access to healthcare by keeping essential services in rural communities. To accomplish this goal, CAHs receive certain benefits, such as cost-based reimbursement for Medicaid services.
CJR	Comprehensive Care for Joint Replacement model
CDS	Clinical Data Support Systems
Center of Excellence	Generally, a hospital self-designation of a specific package of services aimed at treating a specific disease (e.g., bariatric surgery services, stroke care, breast care). COEs tend to be narrower in the range of services included than a service line (e.g., cardiovascular services, orthopedics).
CMS	Centers for Medicare and Medicaid Services

Term	Meaning
CoPs	Medicare Conditions of Participation
Covered Entity	A covered entity under HIPAA is a health plan; a health care clearinghouse; or a health care provider who conducts certain financial and administrative transactions electronically. (These electronic transactions are those for which standards have been adopted by the Secretary under HIPAA, such as electronic billing and fund transfers.)
CPC	Comprehensive Primary Care
CPC+	Comprehensive Primary Care Plus
CRT	Complex Rehabilitation Technology
EC	MIPS Eligible Clinicians
EHR	An Electronic Health Record (EHR) is an electronic version of a patient's medical history, that is maintained by the provider over time, and may include all of the key administrative clinical data relevant to that persons care under a particular provider, including demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports. While an EHR does contain the medical and treatment histories of patients, an EHR system is built to go beyond standard clinical data collected in a provider's office and can be inclusive of a broader view of a patient's care.
ePHI	Electronic protected health information (ePHI) refers to any protected health information (PHI) that is covered under Health Insurance Portability and Accountability Act of 1996 (HIPAA) security regulations and is produced, saved, transferred or received in an electronic form.
ERISA	Employee Retirement Income Security Act of 1974
ESRD	End Stage Renal Disease
FWA	Fraud, Waste and Abuse
FDR	First Tier, Downstream and Related Entity. Used in identify providers and entities furnishing services to Medicare Advantage organization or Part D plan sponsor.
Gainsharing	Gainsharing, or provider incentive programs, allow physicians and hospitals to share remuneration for implementing and coordinating improvements in efficiency and quality.
GINA	The Genetic Information Nondiscrimination Act of 2008 (GINA) is a federal law that protects individuals from genetic discrimination in health insurance and employment. Genetic discrimination is the misuse of genetic information.
GPCI	Geographic Practice Cost Index. The Medicare physician fee schedule amounts are adjusted to reflect the variation in practice costs from area to area. A GPCI has been established for every Medicare payment locality for each of the three

Term	Meaning
	components of a procedure's relative value unit (i.e., the RVUs for work, practice expenses, and malpractice). The GPCIs are applied in the calculation of a fee schedule payment amount by multiplying the RVU for each component times the GPCI for that component.
HCPCS	Healthcare Common Procedure Coding System
HHA	Home Health Agency
HIPAA	The Health Insurance Portability and Accountability Act of 1996 consists of five titles: • Title I of HIPAA protects health insurance coverage for workers and their families when they change or lose their jobs. • Title II of HIPAA establishes policies and procedures for maintaining the privacy and security of individually identifiable health information. In addition, Title II includes the Administrative Simplification (AS) provisions, which require the establishment of national standards for electronic health care transactions and national identifiers for providers, health insurance plans, and employers. • Title III sets guidelines for pre-tax medical spending accounts. • Title IV sets guidelines for group health plans. • Title V governs company-owned life insurance policies.
HITECH	The Health Information Technology for Economic and Clinical Health Act (HITECH Act) was enacted under Title XIII of the American Recovery and Reinvestment Act of 2009 (Pub.L. 111–5) was created to motivate the implementation of electronic health records (EHR) and supporting technology in the United States. HITECH expanded the scope of privacy and security protections available under HIPAA; increased the potential legal liability for non-compliance; and provides for more stringent enforcement. HITECH provides that by the beginning of 2011, healthcare providers will be given monetary incentives for being able to demonstrate meaningful use of electronic health records (EHR).
HOPD	Hospital Outpatient Department
HPI	History of present illness
HRA	Health Reimbursement Agreements are employer-funded accounts that employees can use to pay for health insurance premiums or medical expenses.
HRSA	The Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services, is the primary federal agency for improving health care to people who are geographically isolated, economically or medically vulnerable.

Term	Meaning
IOTP	Intensive Outpatient Treatment Program
IPPS	Inpatient Prospective Payment System
IRMAA	Income Related Monthly Adjustment Amounts. A Medicare beneficiary whose income exceeds a threshold pays a IRMAA towards the Medicare Part B premium.
IRO	Independent Review Organizations are entities that conduct independent external reviews of adverse determinations involving appropriateness of care, medical necessity criteria, level of care, and effectiveness of a requested service.
LEJR	Lower extremity joint replacements
LTCH	Long Term Care Hospital
MBI	Medicare Beneficiary Identifier
MACRA	The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)
MDM	Medical Decision Making
MedPAC	The Medicare Payment Advisory Commission (MedPAC) is an independent US federal body established by the Balanced Budget Act of 1997 (P.L. 105-33). Its primary role is to advise Congress on payments to private health plans participating in Medicare and health providers serving Medicare beneficiaries.
MIO	Medically Ill Offender
MIO TCRA	Medically Ill Offender Treatment and Crime Reduction Act
MIPS	Merit-based Incentive Payment System (MIPS)
NPP	Nonphysician Practitioner. Includes physician assistants (PAs), advanced practice nurses (APNs), clinical nurse specialists (CNSs), certified nurse midwives (CNMs), and certified registered nurse anesthetists (CRNAs).
OCR	The U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) enforces federal civil rights laws, conscience and religious freedom laws, the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, and Breach Notification Rules, and the Patient Safety Act and Rule.
ONC	The Office of the National Coordinator for Health Information Technology (ONC) is a staff division of the Office of the Secretary, within the U.S. Department of Health and Human Services. ONC leads national health IT efforts, charged as the principal federal entity to coordinate nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information.
OP	Outpatient Procedure
OPPS	Outpatient Prospective Payment System
QPP	Quality Payment Program

Term	Meaning
QPP API	Quality Payment Program Application Programming Interfaces
OPT	Opioid Treatment Program
PDGM	Patient-Driven Groupings Model is a case-mix reimbursement system that relies on patient characteristics to more accurately pay for home health services.
PHI	Protected health information (PHI) is any information about health status, provision of health care, or payment for health care that is created or collected by a Covered Entity (or a Business Associate of a Covered Entity), and can be linked to a specific individual. This is interpreted rather broadly and includes any part of a patient's medical record or payment history. PHI is often sought out in datasets for de-identification before researchers share the dataset publicly. Researchers remove PHI from a dataset to preserve privacy for research participants.
Population Health	Population health has been defined as the health outcomes of a group of individuals, including the distribution of such outcomes within the group.
RPM	Remote Patient Monitoring
SAM	The General Services Administration's System for Award Management (includes an exclusion list).
Schedule I	Schedule I drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse. Some examples of Schedule I drugs are: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone, and peyote.
Schedule II	Schedule II drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous. Some examples of Schedule II drugs are: Combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin.
Schedule III	Schedule III drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence. Schedule III drugs abuse potential is less than Schedule I and Schedule II drugs but more than Schedule IV. Some examples of Schedule III drugs are:

Term	Meaning
	Products containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine), ketamine, anabolic steroids, testosterone.
Schedule IV	Schedule IV drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence. Some examples of Schedule IV drugs are: Xanax, Soma, Darvon, Darvocet, Valium, Ativan, Talwin, Ambien, Tramadol
Schedule V	Schedule V drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes. Some examples of Schedule V drugs are: cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin AC), Lomotil, Motofen, Lyrica, Parepectolin
SUD	Substance Use Disorder
TEO	Tax-Exempt Organization
Tarasoff	Tarasoff v. Regents of the University of California, 17 Cal. 3d 425, 551 P.2d 334, 131 Cal. Rptr. 14 (Cal. 1976), was a case in which the Supreme Court of California held that mental health professionals have a duty to protect individuals who are being threatened with bodily harm by a patient. The professional may discharge the duty in several ways, including notifying police, warning the intended victim, and/or taking other reasonable steps to protect the threatened individual.
TPO	Treatment, Payment and Operations. Under HIPAA, a covered entity may share PHI with another covered entity or business associate without the need for a patient's authorization for purposes of PTO, such as to treat the patient's illness, receive payment for services rendered, or to engage in quality checks and case management in an effort to enhance health care operations.
340B	The 340B Drug Discount Program is a program administered by HRSA that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices.
1115 Waivers	A state Medicaid program's application for federal permission to depart from Medicaid's usual rules.

Medicare and Medicaid Basics

Joseph Milestone, Esq.
Rutgers University

RUTGERS
New Jersey Medical School

RUTGERS
Cancer Institute
of New Jersey

RUTGERS
BIOMEDICAL AND
HEALTH SCIENCES

RUTGERS Robert Wood Johnson Medical School

RUTGERS
University Behavioral
Health Care

RUTGERS
School of Nursing

RUTGERS
Ernest Mario School
of Pharmacy

EOHSI
Environmental & Occupational Health Sciences Institute

RUTGERS
EMERGENCY
SERVICES
THE STATE UNIVERSITY
NJ

1766-2016
RUTGERS
250

Medicare – Title XVIII
Medicaid – Title XIX
Evaluation & Management Services

"For me, crime pays for what Medicare doesn't cover."

Medicare

- Part A – Hospital Insurance
- Part B – Supplementary Medical Insurance
- Part C – Medicare Advantage
- Part D – Prescription Drugs

Medicare Part A

- Inpatient Hospital Care
- Outpatient Hospital Care
- Skilled Nursing Facility (SNF) Care
- Home Health Services
- Hospice Care

- Funded by payroll tax contributions (FICA)
- No premium payments for those automatically eligible
  - Age 65
  - Disabled (entitled to Social Security)
  - End Stage Renal Disease (dialysis or kidney transplant)

Medicare Part B
Supplementary Medical Insurance – SMI

Medical and Other Health Services

- Physician Services (Office and Hospital Outpatient Department)
- Outpatient Hospital Department Services
- Laboratory Services
- Home Health Care
- PT/OT
- Durable Medical Equipment
- Diagnostic Imaging
- X-ray/Radiation Therapy
- Ambulance Services
- Home Dialysis
- Vaccines
- Mammography
- Clinical Psychologists/Social Workers

Medicare Part B

- Annual deductible – $233.00
- Medicare approved charges – Fee-for-Service

  80% (Medicare) + 20% (beneficiary)
- Premiums deducted from Social Security checks
- Premiums based on modified gross income
  - Individuals yearly income less than $91,000 – $170.10/month

Medicare Part C
Medicare Advantage
(formerly Medicare + Choice)

Medicare Managed Care

- Replaces original Part A and Part B coverage
- Generally provides all the items/services offered by Parts A and B
- Additional Benefits
  - Prescription Drugs
  - Vision
  - Dental
  - Hearing
  - Wellness Programs

Medicare Part D
Prescription Drug Coverage

- Prescription Drugs
- Biologicals
- Vaccines
- Premiums nationally average $51.00/month for enhanced plans
- “Donut Hole”

Medigap
Supplemental Policies

- Coverage for coinsurance and deductibles
- Ten Standard Medigap Plans: A-D, F, G, K-N
- All plans with the same letter offer the same benefits

Terminology and Program Administration

- CMS f/k/a HCFA
- Assignment
- Reassignment
- Medicare Administrative Contractors (MACs)
  - Previously – Fiscal Intermediaries (Part A) and Carriers (Part B)
- Medicare Secondary Payor Rule

Medicare Enrollment for Providers/Suppliers

- National Provider Identifier (NPI)
- Provider Enrollment, Chain and Ownership System (PECOS)
  - CMS-855I (Physicians)
  - CMS-855B (Groups)
  - CMS-855R (Reassignment)
- Participating and Non-Participating Physicians
- Private Contracting – “Concierge Medicine”
- Loss of Medicare Billing Privileges

Coverage and Reimbursement
Medicare Part A

Prospective Payment System (PPS)

- Hospital Inpatient Services (IPPS)
- Hospital Outpatient Services (HOPPS)
- Skilled Nursing Services (RUGS)
- Home Health Care Services (HHRG)
  - First 100 Days – Part A
- Hospice Services

Coverage and Reimbursement Medicare Part B

- Physician Services
- Nonphysician Services (CRNA, PA, LCSW, CNM)
- “Incident to” Supplies (drugs)
- Outpatient Department Services
- Diagnostic Laboratory Services
- DMEPOS
- Ambulance
- PT/Speech
- Vaccines

Coverage and Reimbursement Medicare Part B

Physician Fee Schedule

- Published Annually
- Over 10,000 services are listed in the PFS
- Fees are based on CPT codes
- Calculated according to RBRVS

“Incident to” Services

Permits a physician to bill for services performed by “physician extenders”

- Physician
- NP
- CNM
- PA
- Psychologists
- LCSW
- PT/OT

- Direct Supervision
  - Area where care is delivered
  - Immediately available
- Plan of Care

Technical
vs.
Professional Components

- Physician Component and Technical Component
  - Diagnostic Tests
- Professional Component (PC)
  - Modifier “26”
- Technical Component – Modifier “TC”
- Global Fee – Both PC and TC

Anti-Markup Rule

- Purchased TC or PC

Resource Based Relative Value Scale (RBRVS)

- RBRVS assigns to each particular service/procedure (CPT code) values for:
  - physician work
  - practice expense
  - malpractice expense
- RVUs – Most physicians are compensated in part on Physician Work Relative Value Units (wRVUs)

CMS Manual System

- 26 Online Manuals
- 3 Paper-Based Manual
- Policy Statements NOT Binding Authority
- Garland Memo

Alternative Payment Models

- Types of Alternative Payment Models (APMs)
  - Accountable Care Organizations (ACOs)
    - Medicare Shared Savings Program (MSSP)
  - Bundled Payments
    - BPCI–Advanced
    - CJR
  - Patient Centered Medical Homes (PCMH)
  - CPC+/PCF
- Medicare Access & CHIP Reauthorization Act of 2015 (MACRA)

Merit Based Incentive Payment System (MIPS)

- Payments based on physician performance:
  - Quality
  - Advancing care information
  - Cost
  - Improvement activities
- “Mandatory Voluntary”
- Payment Adjustments

Advanced Alternative Payment Models (APMs)

- Advanced APMs are special alternative payment models
  - Certified electronic health record (EHR) technology
  - MIPS-comparable quality metrics
  - Medical home model OR bear more than nominal financial risk
- No MIPS reporting and reimbursement - applicable advanced APM requirements instead

Population Health, Risk-Based Models and Health Equity

- Population Health
- Risk-Based Payment Models
- Types of Risks Included in a Risk-Based Payment Model
- Triple Aim
- Health Disparity, Equality and Equity

TELEMEDICINE

- Telehealth During COVID
- Virtual Check-Ins (HCPCS Code G2012)
- E-Visits

Medicaid

- Title XIX
- 1965
- Medical Assistance for families receiving welfare
  - Poor families with dependent children
  - Poor aged, blind and disabled
- Funded jointly by federal and state governments

FamilyCare Program

- New Jersey Department of Human Services (DHS)
- Division of Medical Assistance and Health Services (DMAHS)
  - 1.8 million beneficiaries
  - 1 out of 5 residents
  - 1 in 3 children
  - 5 in 9 nursing home residents
  - 1 in 3 individuals with disabilities
  - 1 in 7 Medicare beneficiaries

Categorically Needy

- Categorically Needy – Mandatory Eligibility
  - Children (up to age 19)
- Parents/Caretakers (income below 138% FPL)
  - Adults age 19-64 (income below 138% FPL)
  - Aged, blind or disabled (receiving SSI)
  - Pregnant People (income below 205% FPL)
- Medically Needy
  - No longer a classification
  - Coverage provided through FamilyCare
- CHIP
- QMBs

Medicaid Managed Care

- FamilyCare is a managed care program
  - Aetna Better Health of New Jersey
  - AmeriGroup of New Jersey
  - Horizon NJ Health
  - UnitedHealthcare Community Plan
  - WellCare (acquired Healthfirst NJ)
- Enrollment through Gainwell Technologies
- Non-Billing Provider
  - FamilyCare/FFS/Charity Care

Medicaid Mandatory Services

- Inpatient and outpatient hospital treatment
- Laboratory tests and X-rays
- Early and Periodic Screening, Diagnosis and Treatment (EPSDT)
- Home health care
- Physician Services
- Nursing Facilities

Optional Medicaid Services

- Dental Care
- Eyeglasses
- Psychologist
- Podiatrist
- Drugs
- DME
- Hearing Aids
- Transportation
- PT/OT/Speech

Medicaid Reimbursement

- Generally low – About half of Medicare for primary care, pediatrics and obstetrics
- New Jersey – lowest Medicaid participation nationally
- Out-of-State Hospitals

Terms and Concepts

- **Qualified Medicare Beneficiaries (QMBs)**
  - "Dual Eligibles"
  - Medicaid pays Medicare premiums, deductibles and co-pays

Medicaid Third Party Liability

- "Payor of Last Resort"

Medicaid Estate Recoveries

Evaluation and Management Services (E&M Codes)

- AMA – Current Procedural Terminology – CPT codes
- Medicare – Healthcare Common Procedure Coding System – HCPCS
- Primary Care Physicians – majority of patient care services
- New E&M Codes – effective January 1, 2021
- Selection based on MDM or time

Established Office Patients

Number and Complexity of Problems Addressed	Amount and/or Complexity of Data to be Reviewed and Analyzed	Risk of Complications and/or Morbidity or Mortality of Patient Management	MDM	Code Level
• 1 self-limited or minor problem [for example, cold, insect bite, tinea corporis (ringworm)]	Minimal or none [Diagnostic Procedures Ordered: laboratory tests requiring venipuncture, chest x-rays, EKG/EEG, urinalysis, ultrasound (ex. Echocardiography, KOH prep (diagnoses ringworm)]	Minimal risk of morbidity from additional diagnostic testing or treatment [Management Options Selected: rest, gargles, elastic bandages, superficial dressings]	SF	99202 99212
• 2 or more self-limited or minor problems OR • 1 stable chronic illness [for example, well controlled hypertension, non-insulin dependent diabetes, cataract, BPH (benign prostatic hyperplasia)] OR • 1 acute, uncomplicated illness or injury [for example, cystitis, allergic rhinitis, simple sprain]	(Must meet the requirements of at least 1 of the 2 categories) Category 1: Tests and Documents Any combination of 2 of the following: • Review of prior external note(s) from each unique source • Review of the result(s) of each unique test Or Category 2: Assessment requiring an independent historian(s) [Diagnostic Procedures Ordered: physiologic test not under stress (for example, pulmonary function tests), non-cardiovascular imaging studies with contrast (for example, barium enema), superficial needle biopsies, clinical laboratory tests requiring arterial puncture, skin biopsies]	Low risk of morbidity from additional diagnostic testing or treatment [Management Options Selected: OTC drugs, minor surgery with no identified risk factors, PT, OT, IV fluids w/o additives]	Low	99203 99213

Established Office Patients (con't)

Number and Complexity of Problems Addressed	Amount and/or Complexity of Data to be Reviewed and Analyzed	Risk of Complications and/or Morbidity or Mortality of Patient Management	MDM	Code Level
• 1 or more chronic illnesses with mild exacerbation, progression, or side effects of treatment; OR • 2 or more stable chronic illnesses; OR • 1 undiagnosed new problem with uncertain prognosis [for example, breast lump]; OR • 1 acute illness with systemic symptoms [for example, pyelonephritis (UTI), pneumonitis (lung inflammation), colitis] OR • 1 acute complicated injury [for example, head injury with brief loss of consciousness]	(Must meet the criteria of at least 1 of the 3 categories) Category 1: Tests, Documents, or independent historian(s) Any combination of 3 of the following: • Review of prior external note(s) from each unique source • Review of the result(s) of each unique test • Ordering of each unique test • Assessment requiring an independent historian(s) OR Category 2: Independent interpretation of tests; Independent interpretation of a test performed by another physician/qualified health care professional (not separately reported) OR Category 3: Discussion of management or test interpretation; Discussion of management or test interpretation with external physician/ other qualified health care professional/ appropriate source (not separately reported) [Diagnostic Procedures Ordered: physiologic tests under stress (for example, cardiac stress test, fetal contraction stress test), diagnostic endoscopies with no identified risk factors,	Moderate Examples only: • Prescription drug management • Decision regarding minor surgery with identified patient or procedure risk factors; • Decision regarding elective major surgery without identified patient or procedure risk factors • Diagnosis or treatment significantly limited by social determinates of health [Management Options Selected: minor surgery with identified risk factors, elective major surgery (open, percutaneous or endoscopic) with no identified risk factors, prescription drug management, therapeutic nuclear medicine, IV fluids with additives, closed treatment of fracture or dislocation without manipulation]	Mod	99204 99214

Established Office Patients (con't)

Number and Complexity of Problems Addressed	Amount and/or Complexity of Data to be Reviewed and Analyzed	Risk of Complications and/or Morbidity or Mortality of Patient Management	MDM	Code Level
	deep needle or incisional biopsy, cardiovascular imaging studies with contrast and no identified risk factors (for example, arteriogram, cardiac catheterization), obtain fluid from body cavity (for example, lumbar puncture, thoracentesis, culdocentesis)]			
• 1 or more chronic illnesses with severe exacerbation, progression, or side effects of treatment OR • acute or chronic illness or injury that pose a threat to life or bodily function [for example, multiple trauma, acute MI, pulmonary embolus, severe respiratory distress, progressive rheumatoid arthritis, psychiatric illness with potential threat to self or others, peritonitis, acute renal failure] OR • an abrupt change in neurologic status [for example, seizure, TIA	Category 1: Tests, Documents, or independent historian(s) Any combination of 3 of the following: • Review of prior external note(s) from each unique source • Review of the result(s) of each unique test • Ordering of each unique test • Assessment requiring an independent historian(s) OR Category 2: Independent interpretation of tests; Independent interpretation of a test performed by another physician/qualified health care professional (not separately reported) OR Category 3: Discussion of management or test interpretation; Discussion of management or test interpretation with external physician/ other qualified health care professional/ appropriate source (not separately reported)	High Examples only: • Drug therapy requiring intensive monitoring for toxicity • Decision regarding elective major surgery with identified patient or procedure risk factors • Decision regarding emergency major surgery • Decision regarding hospitalization • Decision not to resuscitate or to de-escalate care because of poor prognosis [Management Options Selected: elective major surgery (open, percutaneous or endoscopic) with identified risk factors, emergency major surgery (open, percutaneous or endoscopic), parenteral controlled substances, drug therapy requiring intensive monitoring for toxicity, decision not to resuscitate or to	High	99205 99215

Established Office Patients (con't)

Number and Complexity of Problems Addressed	Amount and/or Complexity of Data to be Reviewed and Analyzed	Risk of Complications and/or Morbidity or Mortality of Patient Management	MDM	Code Level
(similar to a stroke), weakness, sensory loss]	[Diagnostic Procedures Ordered: cardiovascular imaging studies with contrast with identified risk factors, cardiac electrophysiological tests, diagnostic endoscopies with identified risk factors, discography]	de-escalate care because of poor prognosis]		

Anatomy of an OIG Investigation

Implications and Stop-Gap Measures for Compliance Professionals

Presented by:
Eric Rubenstein
Special Agent (ret.)
HHS-OIG
Director, Litigation, Fraud, Waste and Abuse Support
Advize Health LLC


EXIT
pancake house
www.pancakes.com
PJ's Famous Pancakes

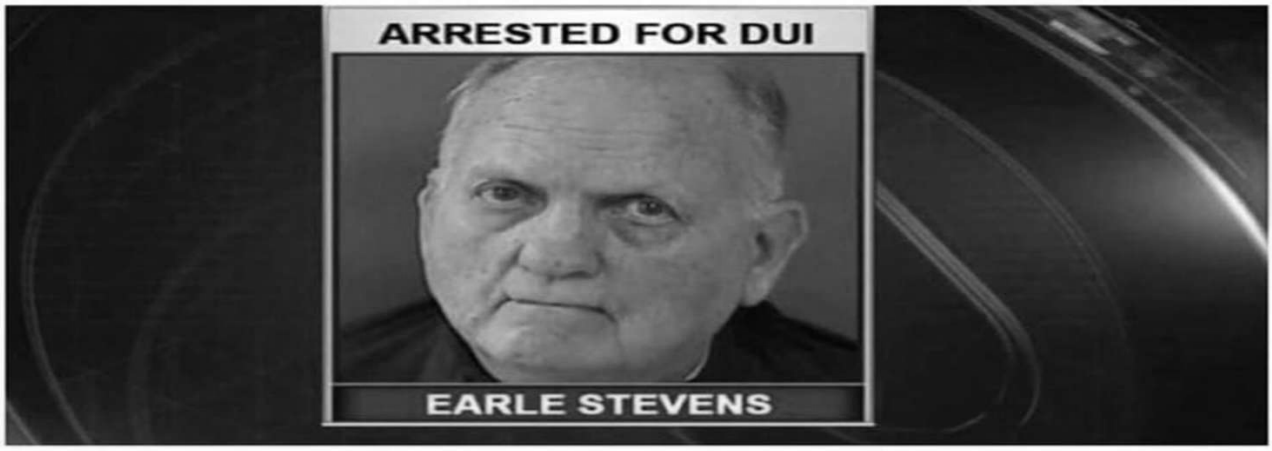
PRESENTATION AGENDA

- Initiation of an OIG investigation
  - Where are cases derived
  - OIG Investigative considerations
  - Role of UPICS/MEDIC/MAC
    - The alphabet soup of healthcare fraud investigations
- Lifecycle of an Investigation
- Suggested areas to target for compliance

BUT FIRST.....


ITALIAN
AUSAGE
16

Florida man claims he only drank at stoplights, and not while driving



CASE ORIGINS

- Sources of complaints can be both reactive and proactive
- Relators (whistleblowers)
  - 1-800-HHS-TIPS (the "Hotline")
  - 1-800-Medicare
  - Mail in
  - Telephone calls to OIG offices directly
  - Walk-in
  - Healthcare fraud partners (other law enforcement organizations, insurance carriers)
  - UPIC/MEDIC referrals
  - Proactive data analysis
  - The Healthcare Fraud Prevention Partnership (HFPP)
  - Cooperating Witnesses and Sources

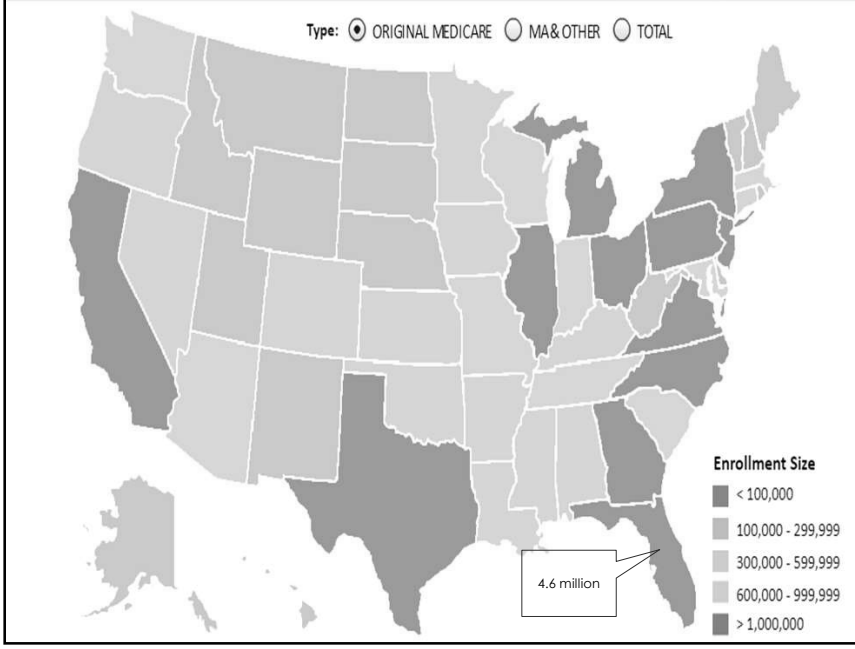
A Hotline Complaint

COMMENTS:

MS. [redacted] IS A SOCIAL WORKER AT [redacted] TOWER WEST, A SENIOR HOUSING RESIDENCE. SHE CALLED ON BEHALF OF ONE THE RESIDENTS, [redacted] RECEIVED A BENEFITS NOTICE SHOWING THAT PREMIUM MEDICAL CARE BILLED MEDICARE $180.26 ($180.26 APPROVED) FOR 1 HOME VISIT, NEW PATIENT (99344) ON 7/12/05. MR. [redacted] HAD RESPONDED TO AN AD FOR "FREE BALANCE SCREENINGS" OFFERED AT THE HOME. MS. [redacted] STATED THAT AT LEAST 25 RESIDENTS WERE SEEN THAT DAY, AND WHILE MR. [redacted] ACTUALLY RECEIVED A BALANCE SCREENING, MOST SIMPLY HAD THEIR BLOOD PRESSURE TAKEN. [redacted]

OIG HEAVY RELIANCE ON DATA ANALYTICS-A/B and MA Enrollment

Hospital/Medical Enrollment, October 2020 — Count



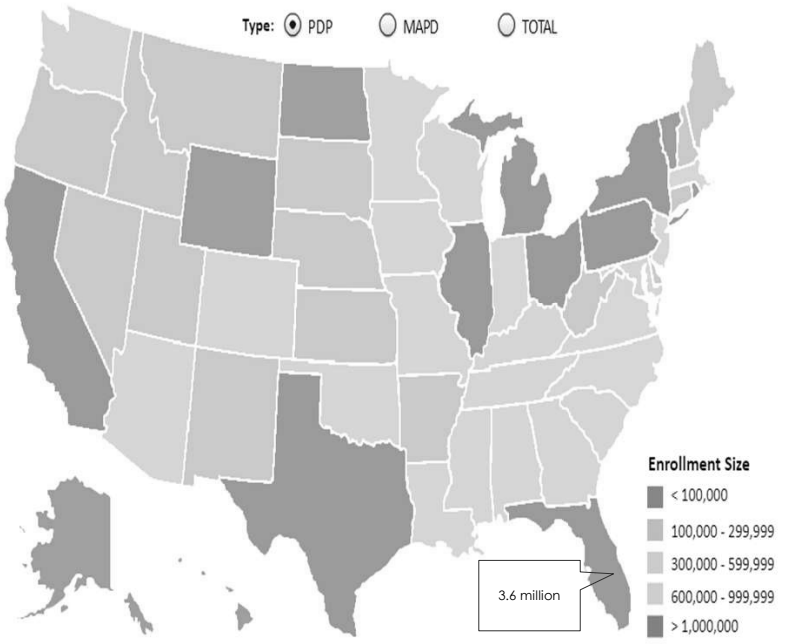
Hospital/Medical Enrollment Counts by Month

ALL AREAS

Year	Month	Original Medicare	Medicare Advantage & Other Health Plans	Total
2019	November	38,829,209	23,283,410	62,112,619
	December	38,919,031	23,305,980	62,225,011
2020	January	37,710,992	24,648,529	62,359,521
	February	37,738,714	24,691,585	62,430,299
	March	37,766,258	24,767,292	62,533,550
	April	37,750,925	24,837,478	62,588,403
	May	37,711,014	24,893,393	62,604,407
	June	37,698,155	24,967,033	62,665,188
	July	37,643,438	25,122,781	62,766,219
	August	37,622,349	25,219,972	62,842,321
	September	37,597,135	25,315,846	62,912,981
	October	37,571,473	25,410,841	62,982,314

PART D ENROLLMENT

Prescription Drug Enrollment, October 2020 Count



Prescription Drug Enrollment Counts by Month

ALL AREAS

Year	Month	Prescription Drug Plans	Medicare Advantage Prescription Drug	Total
2019	November	25,664,717	20,589,910	46,254,627
	December	25,683,827	20,615,156	46,298,983
2020	January	25,240,829	21,815,185	47,056,014
	February	25,223,948	21,865,604	47,089,552
	March	25,192,725	21,944,412	47,137,137
	April	25,201,296	22,018,782	47,220,078
	May	25,177,228	22,078,576	47,255,804
	June	25,176,394	22,153,085	47,329,479
	July	25,170,134	22,304,077	47,474,211
	August	25,143,590	22,398,268	47,541,858
	September	25,146,689	22,492,254	47,638,943
	October	25,118,173	22,586,902	47,705,075

DATA, DATA, DATA

- Trends in provider billings
- Trends in specialties
- Trends in prescribing
- OEI/OAS studies
- OIG Workplan

HOW DATA CAN SUPPORT AN ALLEGATION

2001
Of Unique HICs Between and HHA - 234
Of Unique HICs For - 2,267
10% of patients were receiving home health services at the time of podiatry service
2002
Of Unique HICs Between and HHA - 233
Of Unique HICs For - 2,390
10% of patients were receiving home health services at the time of podiatry service
2003
Of Unique HICs Between and HHA - 243
Of Unique HICs For - 2,521
10% of patients were receiving home health services at the time of podiatry service
2004
Of Unique HICs Between and HHA - 245
Of Unique HICs For - 2,529
10% of patients were receiving home health services at the time of podiatry service
2005
Of Unique HICs Between and HHA - 43
Of Unique HICs For - 808
5% of patients were receiving home health services at the time of podiatry service

IN THE PHARMACY SPACE

BIAXIN XL								
YEAR	HD SMITH	KINRAY	AMERISOURCE	TOTAL	TOWNE	DIFFERENCE	AVG PILL PRICE	OVERAGE
2002	0	1800	4620	6420	11883	5463	$4.07	$22,234.41
2003	0	1920	14160	16080	18424	2344	$4.17	$9,774.48
2004	0	720	8220	8940	14257	5317	$4.33	$23,022.61
2005	0	1260	120	1380	10438	9058	$4.54	$41,123.32
							TOTAL	$96,154.82
CLARITHROMYCIN ER								
2001	0	0	0	0	0	0	$0.00	$0.00
2002	0	0	0	0	0	0	$0.00	$0.00
2003	0	0	0	0	0	0	$0.00	$0.00
2004	0	0	0	0	0	0	$0.00	$0.00
2005	0	0	0	0	0	0	$0.00	$0.00
2006	0	0	0	0	632	632	$4.24	$2,679.68
							TOTAL	$2,679.68

OIG INVESTIGATIVE LIFECYCLE

- Receipt of complaint
- Vetting of complaint
- Interviews
- Data analysis
- Document reviews
- Subpoenas (various types)

OIG CONSIDERATIONS

- What is the estimated loss amount
  - SVRS/Actual
- What are office/agency priorities
  - Strikeforce/Qui Tam
- What is the origin of the complaint
  - Known/unknown complainant
- Is there a patient harm issue
  - Detroit cancer doctor-Farid Fata
- What is the US Attorney's Office priority

THE ALPHABET SOUP OF MEDICARE CONTRACTORS-ROLES

- UPIC (Parts A, B—including DME)
  - 5 regions
- MEDIC
  - Part C and D
- MAC

INVESTIGATIVE LIFECYCLE

- Complaints may be unfounded but other issues may be identified
- Interviews lead to other interviews
- Data analysis leads to other data analysis
- Document reviews lead to other document reviews
- Criminal investigations-Search Warrants

COMPIANCE CONSIDERATIONS-LAW ENFORCEMENT

- Do you have a policy in place if law enforcement attempts to interview current employees
- Is there a policy in place if law enforcement shows up with a search warrant
- Is there a policy in place if subpoenas are served for documents/testimony

OTHER COMPLIANCE CONSIDERATIONS

- What is the policy on proactive data analysis for billing trends
- What is the policy for proactive reviews of medical records for proper coding
- What is the policy for data/electronic record retention
- Reviewing OIG and DOJ compliance guidance
- Are contracts reviewed for Stark/AKS violation considerations
  - Rental agreements
  - Employment/1099 considerations
  - General Fair Market Value discussions
- Exclusions related issues
- Reporting violations and issues

CODERS AND AUDITORS CAN BE PART OF THE FRAUD

- Criminal liability
- Civil liability
- CMPL liability

Mary Talaga, 54, of Elmwood Park, Illinois, was convicted in May 2015 following a jury trial of one count of conspiracy to commit health care fraud, six counts of health care fraud and three counts of false statements relating to a health care matter. In addition to imposing the prison term, U.S. District Judge Gary Feinerman of the Northern District of Illinois ordered Talaga to pay approximately $1 million in restitution.

From 2007 to 2011, Talaga was the primary medical biller at Medicall Physicians Group Ltd., a physician practice that visited patients in their homes and prescribed home health care. The evidence at trial showed that Talaga and her co-conspirators routinely billed Medicare for overseeing patient care plans (a service known as "care plan oversight" or CPO) when, in fact, the doctors at Medicall rarely provided the service. The evidence at trial also showed that Talaga and her co-conspirators billed Medicare for other services that were never provided, including services rendered to patients who were deceased, services purportedly provided by medical professionals no longer employed by Medicall, and services purportedly provided by medical professionals who, based on billing records, worked over 24 hours per day.

According to the evidence presented at trial, during the five-year conspiracy, Medicall submitted bills to Medicare for more than $4 million in services that were never provided. Medicare paid more than $1 million on those claims.

Rick Brown, 58, of Rockford, Illinois, and Roger A. Lucero, 64, of Elmhurst, Illinois, were also convicted of offenses based on their roles in the scheme. Brown was convicted along with Talaga at trial and was previously sentenced to serve more than seven years in prison. Lucero, Medicall's Medical Director, pleaded guilty and will be sentenced at a later date.

The owner and operator of a New Jersey billing company will pay a $100,000 penalty after submitting fraudulent Medicare claims for diagnostic tests that were never conducted, marking the first such penalty for a billing company from HHS' Office of Inspector General.

Susan Toy and her company, Millennium Billing, submitted claims to Medicare for a physician-owned obstetrics and gynecology practice, knowing that the underlying diagnostic tests were never performed, according to the OIG. She received compensation from the practice—the Center for Advanced Pelvic Surgery—for these actions.

The first-of-its-kind penalty, HHS OIG spokesman Donald White said, demonstrates that OIG expects "compliance throughout the full range of federal healthcare program processes."

CONTACT INFORMATION

Advizehealth.com

Eric Rubenstein
Director of Litigation Support, FWA
erubenstein@advizehealth.com

Jeanmarie Loria
CEO
jloria@advizeheath.com

This page intentionally left blank

MEDICARE AND MEDICAID SPECIAL ISSUES

Presented by

LISA D. TAYLOR, ESQ.

Sequestration

Sequestration is a reduction in federal spending by a certain percentage. As this applies to Medicare, the reduction in federal spending means providers receive less payment for services, specifically by two percent.

Sequestration is required by the Budget Control Act that was signed into law in August 2011. It was originally intended as an incentive to achieve $1.2 trillion in budget savings.

Sequestration

An Act to Prevent Across-the-Board Direct Spending Cuts, and for Other Purposes, signed into law on April 14, 2021 extended the suspension period to December 31, 2021.

The Protecting Medicare and American Farmers from Sequester Cuts Act was signed into law in December 2021 extending the suspension until March 31, 2021.

Sequestration

From April 2022 through June 2022 a 1% sequester cut will be in effect, with the full 2% cut resuming thereafter.

Medicare Deactivation

The Centers for Medicare and Medicaid Services may deactivate the Medicare billing privileges of a provider or supplier for a number of reasons including the following:

1. The provider or supplier does not submit any Medicare claims for 12 consecutive calendar months.
2. The provider or supplier does not report a change to the information supplied on the enrollment application within 90 calendar days of when the change occurred. Changes that must be reported include, but are not limited to, a change in practice location, a change of any managing employee, and a change in billing services. A change in ownership or control must be reported within 30 calendar days as specified in 42 C.F.R. §§ 424.520(b) and 424.550(b).
3. The provider or supplier does not furnish complete and accurate information and all supporting documentation within 90 calendar days of receipt of notification from CMS to submit an enrollment application and supporting documentation, or resubmit and certify to the accuracy of its enrollment information

Medicare Deactivation

Deactivation of Medicare billing privileges is considered an action to protect the provider or supplier from misuse of its billing number and to protect the Medicare Trust Funds from unnecessary overpayments. The deactivation of Medicare billing privileges does not have any effect on a provider or supplier's participation agreement or any conditions of participation.

However, reactivation can be a time-consuming process.

MLTSS

Managed Long Term Services and Supports (MLTSS) operates under a Medicaid waiver issued to the New Jersey Department of Human Services and is designed to expand home and community-based services, promote community inclusion and ensure quality and efficiency.

Eligibility is based upon financial criteria and clinical criteria including age and disability.

New Jersey's Medicaid managed care organizations coordinate all MLTSS benefits which are provided to beneficiaries at a variety of locating including those residing at home, in an assisted living facility, in community residential services or in a nursing home.

MLTSS includes:

- ❑ Access to all NJ FamilyCare Plan A Benefits;
- ❑ Care Management;
- ❑ Home and Vehicle Modifications;
- ❑ Home Delivered Meals;
- ❑ Respite;
- ❑ Personal Emergency Response Systems;
- ❑ Mental Health and Addiction Services;
- ❑ Assisted Living;
- ❑ Community Residential Services;
- ❑ Nursing Home Care.

QUESTIONS

Thank You

LISA D. TAYLOR, ESQ.
Inglesino, Webster, Wyciskala & Taylor, LLC
600 Parsippany Road, Suite 204
Parsippany, New Jersey 07054
ltaylor@iwwt.law
(973) 947-7135

About the Panelists…

Joseph Milestone is a Senior Associate General Counsel at Rutgers, The State University in New Brunswick, New Jersey, where he is primary counsel to New Jersey Medical School and Robert Wood Johnson Medical School and their affiliated practice plans, which employ more than 1,000 doctors, dentists, psychologists, APNs, PAs and NPPs. He served as a lead counsel in the development of the master affiliation and Supplemental Agreements (MAA) between Rutgers Biomedical and Health Sciences and RWJ Barnabas Health to create the largest academic health system in New Jersey. Prior to joining Rutgers, he served in the Office of Legal Management of the University of Medicine & Dentistry of New Jersey (UMDNJ).

Admitted to practice in New York, New Jersey, Connecticut, and Pennsylvania, Mr. Milestone is a member of the New Jersey State Bar Association, where he is an *emeritus* board member and Past Chair of the Health Law Section. He formerly worked as a health law associate in the Dechert and Pepper Hamilton (now Troutman Pepper) law firms, and was also an Assistant Inspector General in the New Jersey Office of the Inspector General, where he conducted investigations and performed operational and performance reviews of state agencies and programs. He is the recipient of the NJSBA Health Law Section's Distinguished Service Award.

Mr. Milestone received his B.S.E. in Materials Engineering from the University of Pennsylvania and his J.D. from Rutgers University School of Law-Camden, where he was Associate Editor of the *Rutgers Law Journal*.

Eric Rubenstein, MSCJ, CFE is Director of Litigation, Fraud, Waste and Abuse (FWA) Support for Advize Health in Winter Park, Florida, where he provides consulting and advisory work targeting fraud, waste and abuse issues involving health fraud matters. A seasoned retired federal law enforcement officer with 25 years of experience, he formerly specialized in white-collar crime investigations as a Special Agent for the United States Department of Health and Human Services-Office of Inspector General, with wide-ranging experience involving federal healthcare programs.

Mr. Rubenstein is a former member of the IBM UCM project, where he provided subject matter expertise on FWA matters as part of the Optimization Team servicing all UCM user groups (including UPICS, MEDIC and the greater UCM user community-law enforcement). He is also a former member of the Trusted-Third Party for the Healthcare Fraud Prevention Partnership (HFPP), which served the membership of the HFPP and provided SME in FWA and investigative efforts to combat FWA in healthcare. He has more than 20 years of presentation and training facilitation experience and has been a feature presenter/trainer at local, regional and national training academies, conferences (including the National Healthcare Fraud Association and American Association of Professional Coders) and for subject matter case analysis.

Mr. Rubenstein received his B.A. from the University at Buffalo, his M.S. in Criminal Justice/Law Enforcement Administration from the State University of New York College at Buffalo and his Graduate Certificate in Healthcare Administration from the University of North Dakota.

Lisa D. Taylor, Board Certified as an Expert in Health Law by the Florida Bar, is a founding Partner of Inglesino, Webster, Wyciskala & Taylor, LLC in Parsippany, New Jersey, and concentrates her practice in health care law. She handles business and employment transactions, employment and immigration issues, regulatory matters and litigation, and represents professionals in disciplinary matters. She also serves as a neutral arbitrator and mediator, and as an expert witness in health care disputes and professional proceedings.

Admitted to practice in New Jersey, New York, Pennsylvania, Tennessee, Florida and the District of Columbia, and before numerous federal courts, Ms. Taylor is a two non-consecutive term Past Chair of the New Jersey State Bar Association Health Law Section and a member of the Section's *Emeritus* Board, after serving for 20 years on its Board of Directors. She is a Fellow of the American Health Law Association, has held numerous leadership positions with the Association, serves on the Governing Council of the American Bar Association's Health Law Section and is a member of the Health Care Certification Committee of The Florida Bar. She is also a member of the Million Dollar Advocates Forum, which recognizes lawyers who have achieved a trial verdict, award or settlement of $1,000,000 or more.

Ms. Taylor is the recipient of the New Jersey State Bar Association Health & Hospital Law Section's 2007 Distinguished Service Award for service to the health bar and health industry as well as ICLE's Distinguished Service Award for Excellence in Continuing Legal Education in 2014. In 2016 she received the Ira Geller Award from Community Access Unlimited for zealous advocacy of the disabled and in 2004 was one of ten attorneys nationally recognized as Outstanding Physician Practice Lawyers by *Nightingale's Healthcare News*. She is listed in *Who's Who in America*, *Who's Who in American Law* and *Who's Who in the World*, and is the recipient of several other honors.

Ms. Taylor received her undergraduate degree, *cum laude*, from Barnard College, Columbia University, her M.A. in Philosophy from Duke University and her law degree from Duke University. She also studied finance and accounting at Columbia Business School and attended Executive and Continuing Professional Education at Harvard University's T.H. Chan School of Public Health.