CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-01 Medicare General Information, Eligibility, and Entitlement	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 12425	**Date: December 21, 2023**
	Change Request 13496

SUBJECT: Enforcing Billing Requirements for Intensive Outpatient Program (IOP) Services with New Condition Code 92 - Additional Publication Update

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to implement the new condition code 92 for Intensive Outpatient Program (IOP) services and enforce billing requirements.

EFFECTIVE DATE: January 1, 2024
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 2, 2024

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/10.3/Supplementary Medical Insurance (Part B) - A Brief Description
R	4/20/Certification for Hospital Services Covered by the Supplementary Medical Insurance Program
R	5/10/Part A Provider and Related Definitions
R	5/10.1/Provider Agreements

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-01	Transmittal: 12425	Date: December 21, 2023	Change Request: 13496

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EFFECTIVE DATE: January 1, 2024
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I. GENERAL INFORMATION

A. Background: The purpose of this Change Request (CR) is to implement the change in the manual requirements of Chapters 1, 4, and 5, the Medicare General Information, Eligibility and Entitlement Manual 100-01, related to Coverage of Intensive Outpatient Program (IOP) Services, furnished on or After January 1, 2024, finalized in the CY 2024 Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) Final Rule.

B. Policy: Section 4124 of the Consolidated Appropriations Act of 2023 establishes Medicare coverage and payment for IOP services for individuals with mental health needs when furnished by hospital outpatient departments, Critical Access Hospital (CAH) outpatient departments, and CMHCs. The law establishes this new benefit for services furnished on or after January 1, 2024.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
13496 - 01.1	Medicare contractors shall refer to Pub.100-01, the Medicare General Information, Eligibility and Entitlement Manual, chapter 1 section 10.3 for the latest revisions.	X		X						
13496 - 01.2	Medicare contractors shall refer to Pub.100-01, the Medicare General Information, Eligibility and Entitlement Manual, chapter 4 section 20 for the latest revisions.	X		X						
13496 - 01.3	Medicare contractors shall refer to Pub.100-01, the Medicare General Information, Eligibility and Entitlement Manual, chapter 5 sections 10 and 10.1 for the latest revisions.	X		X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13496 - 01.4	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.	X				

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

10.3 - Supplementary Medical Insurance (Part B) - A Brief Description

(Rev. 12425, Issued: 12-21-23, Effective: 01-01-24, Implementation: 01-02-24)

To obtain SMI, an eligible individual must enroll during an enrollment period and pay the required premiums. An individual is eligible to enroll if they are entitled to HI or are 65 years of age and a citizen or resident alien who meets certain residence requirements. SMI provides for payment to participating providers for furnishing covered services after a yearly cash deductible is met. The voluntary medical insurance plan is designed to supplement the basic hospital insurance coverage. It provides coverage for home health visits not available under hospital insurance (e.g., no Part A entitlement or visits after the first 100 visits) and for medical and other health services. Payment may not be made under Part B for any service that may be paid under Part A. However, where payment is not possible under Part A (e.g., no Part A entitlement or benefits are exhausted) payment may be made under Part B if the service is covered.

Subject to coverage and limitations described in the Benefit Policy Publication, the following services are covered under Part B.

- Physicians' services;
- Services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills;
- Hospital services (including drugs and biologicals which are not usually self-administered by the patient) incident to physicians' services rendered to outpatients and partial hospitalization *or intensive outpatient* services incident to such services;
- Diagnostic services which are: (i) furnished to an individual as an outpatient by a hospital or by others under arrangements with them made by a hospital, and (ii) ordinarily furnished by such hospital (or by others under such arrangements) to its outpatients for the purpose of diagnostic study;
- Outpatient physical therapy services, occupational therapy services, and speech-language pathology services;
- Rural health clinic services and Federally qualified health center services;
- Home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies;
- Antigens (subject to quantity limitations prescribed in regulations by the Secretary) prepared by a physician, as defined in section 1861(r)(1) of the Act, for a particular patient, including antigens so prepared which are forwarded to another qualified person (including a rural health clinic) for administration to such patient, from time to time, by or under the supervision of another such physician;
- Services furnished pursuant to a contract under section 1876 of the Act to a member of an eligible organization by a physician assistant or by a nurse practitioner and such services and supplies furnished as an incident to his/her service to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician's service; and, services furnished pursuant to a risk-sharing contract under section 1876(g) of the Act to a member of an eligible

organization by a clinical psychologist (as defined by the Secretary) or by a clinical social worker, and such services and supplies furnished as an incident to such clinical psychologist's services or clinical social worker's services to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician's service;

- Blood clotting factors, for hemophilia patients competent to use such factors to control bleeding without medical or other supervision, and items related to the administration of such factors, subject to utilization controls deemed necessary by the Secretary for the efficient use of such factors;

- Prescription drugs used in immunosuppressive therapy furnished to an individual who receives an organ transplant for which payment is made under this title;

- Services which would be physicians' services if furnished by a physician and which are performed by a physician assistant under the supervision of a physician and which the physician assistant is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as incident to such services as would be covered if furnished incident to a physician's professional service; and but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services.

- Services which would be physicians' services if furnished by a physician and which are performed by a nurse practitioner or clinical nurse specialist working in collaboration with a physician which the nurse practitioner or clinical nurse specialist is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as an incident to such services as would be covered if furnished incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services;

- Certified nurse-midwife services;

- Qualified psychologist services;

- Clinical social worker services;

- Erythropoietin for dialysis patients competent to use such drug without medical or other supervision with respect to the administration of such drug, subject to methods and standards established by the Secretary by regulation for the safe and effective use of such drug, and items related to the administration of such drug;

- Prostate cancer screening tests;

- An oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an anticancer chemotherapeutic agent for a given indication, and containing an active ingredient (or ingredients), which is the same indication and active ingredient (or ingredients) as a drug which the A/B MAC (B) determines would be covered if the drug could not be self-administered;

- Colorectal cancer screening tests;

- Diabetes outpatient self-management training services;

- An oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an acute anti-emetic used as part of an anticancer chemotherapeutic regimen if the drug is administered by a physician (or as prescribed by a physician)-- (i) for use immediately before, at, or within 48 hours after the time of the administration of the anticancer chemotherapeutic agent; and (ii) as a full replacement for the anti-emetic therapy which would otherwise be administered intravenously;

- Screening for glaucoma (as defined in subsection (uu)) for individuals determined to be at high risk for glaucoma, individuals with a family history of glaucoma and individuals with diabetes;

- Medical nutrition therapy services in the case of a beneficiary with diabetes or a renal disease who-- (i) has not received diabetes outpatient self-management training services within a time period determined by the Secretary; (ii) is not receiving maintenance dialysis for which payment is made under section 1881 of the Act; and (iii) meets such other criteria determined by the Secretary after consideration of protocols established by dietitian or nutrition professional organizations;

- Diagnostic X-ray tests (including tests under the supervision of a physician, furnished in a place of residence used as the patient's home, if the performance of such tests meets such conditions relating to health and safety as the Secretary may find necessary and including diagnostic mammography if conducted by a facility that has a certificate (or provisional certificate) issued under section 354 of the Public Health Service Act), diagnostic laboratory tests, and other diagnostic tests; X-ray, radium, and radioactive isotope therapy, including materials and services of technicians;

- Surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations; Durable medical equipment;

- Ambulance service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations;

- Prosthetic and orthotic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens;

- Leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition;

- Vaccines: (1) pneumococcal vaccine and its administration and, subject to section 4071(b) of the Omnibus Budget Reconciliation Act of 1987, (2) influenza vaccine and its administration; and (3) hepatitis B vaccine and its administration, furnished to an individual who is at high or intermediate risk of contracting hepatitis B;

NOTE: A charge separate from the ESRD composite rate will be recognized and paid for administration of the vaccine to ESRD patients.

NOTE: For Medicare program purposes, the hepatitis B vaccine may be administered upon the order of a doctor of medicine or osteopathy by home health agencies, SNFs, renal dialysis facilities (RDFs), hospital outpatient departments, persons recognized under the "incident to physicians' services" provision of law, and, of course, doctors of medicine and osteopathy.

- Services of a certified registered nurse anesthetist;

- Subject to section 4072(e) of the Omnibus Budget Reconciliation Act of 1987, extra-depth shoes with inserts or custom molded shoes with inserts for an individual with diabetes, if-- (1) the physician who is managing the individual's diabetic condition (a) documents that the individual has peripheral neuropathy with evidence of callus formation, a history of pre-ulcerative calluses, a history of previous ulceration, foot deformity, or previous amputation, or poor circulation, and (b) certifies that the individual needs such shoes under a comprehensive plan of care related to the individual's diabetic condition; (2) the particular type of shoes are prescribed by a podiatrist or other qualified physician

(as established by the Secretary); and (3) the shoes are fitted and furnished by a podiatrist or other qualified individual (such as a pedorthist or orthotist, as established by the Secretary) who is not the physician described in (1) above (unless the Secretary finds that the physician is the only such qualified individual in the area);

- Screening mammography;

- Screening pap smear and screening pelvic exam; and

- Bone mass measurement.

- No diagnostic tests performed in any laboratory, including a laboratory that is part of a rural health clinic, or a hospital (which, for purposes of this sentence, means an institution considered a hospital for purposes of section 1814(d)) of the Act shall be included unless such laboratory-

    1. Is situated in any State in which State or applicable local law provides for licensing of establishments of this nature, (1) is licensed pursuant to such law, or (2) is approved, by the agency of such State or locality responsible for licensing establishments of this nature, as meeting the standards established for such licensing;

    2. Meets the certification requirements under section 353 of the Public Health Service Act; and

    3. Meets such other conditions relating to the health and safety of individuals with respect to whom such tests are performed as the Secretary may find necessary.

There shall be excluded from the diagnostic services specified any item or service which would not be included if it were furnished to an inpatient of a hospital. None of the items and services referred to in the preceding paragraphs of this subsection which are furnished to a patient of an institution which meets the definition of a hospital for purposes of section 1814(d) of the Act shall be included unless such other conditions are met as the Secretary may find necessary relating to health and safety of individuals with respect to whom such items and services are furnished.

20 - Certification for Hospital Services Covered by the Supplementary Medical Insurance Program

(Rev. 12425, Issued: 12-21-23, Effective: 01-01-24, Implementation: 01-02-24)

A physician must certify that medical and other health services covered by medical insurance which were provided by (or under arrangement made by) the hospital were medically required.

Physician certification is not required for the following outpatient services furnished on or after January 3, 1968:

- Hospital services and supplies incident to physicians' services rendered to outpatients; and
- Diagnostic services furnished by a hospital or which the hospital arranges to have furnished in other facilities operated by or under the supervision of the hospital or its medical staff.

Hospitals must obtain a physician's certification with respect to other services furnished to outpatients.

Primarily, this means that a certification statement is needed for diagnostic services furnished under arrangements by a facility that is not operated by or under the supervision of the hospital or its organized medical staff, e.g., services obtained from an independent laboratory.

This certification requires a brief description of the services and the signature of the physician. It needs to be made only once for a course of treatment. Where services are provided on a continuing basis, such as a course of radium treatments, the physician's certification may be made at the beginning or end of the course of treatment, or at any other time during the period of treatment.

There is no requirement that the certification be entered on any specific form or handled in any specific way, as long as the approach adopted by the hospital permits the A/B MAC (A) to determine that the certification requirement is in fact met. Therefore, the certification could be entered or pre-printed on a form the physician already has to sign; or a separate certification form could be used.

In addition, physician's certifications are required for the rental and purchase of durable medical equipment (see §70), outpatient therapy, i.e., physical therapy, occupational therapy and speech-language pathology services (see Pub. 100-02, Chapter 15, §220)*, partial hospitalization services (see Pub. 100-02, Chapter 6, § 70.3), and intensive outpatient services (see Pub. 100-02, Chapter 6, § 70.4)*.

The Physician Certification Statement requirements for all ambulance providers (hospital-owned and operated) and suppliers (independently-owned and operated) are located at 42 CFR §410.40 (d) (2) and §410.40 (d) (3).

10 - Part A Provider and Related Definitions

(Rev. 12425, Issued: 12-21-23, Effective: 01-01-24, Implementation: 01-02-24)

Section 1866(e) of the Social Security Act defines the term "provider of services" (or provider) as:

(1) A clinic, rehabilitation agency, or public health agency if, in the case of a clinic or rehabilitation agency, such clinic or agency meets the requirements of section 1861(p)(4)(A) (or meets the requirements of such section through the operation of section 1861(g)), or if, in the case of a public health agency, such agency meets the requirements of section 1861(p)(4)(B) (or meets the requirements of such section through the operation of section 1861(g)), but only with respect to the furnishing of outpatient physical therapy services (as therein defined) or (through the operation of section 1861(g)) with respect to the furnishing of outpatient occupational therapy services; and

(2) A community mental health center (as defined in section 1861(ff)(3)(B)), but only with respect to the furnishing of partial hospitalization services (as described in section 1861(ff)(1)) *or intensive outpatient services (as described in section 1861(ff)(4))*. Definitions of providers, physicians, practitioners, and suppliers, and a description of the requirements that each must meet in order for their services to be considered covered are described in the following sections.

10.1 - Provider Agreements

(Rev. 12425, Issued: 12-21-23, Effective: 01-01-24, Implementation: 01-02-24)

The following provider types must have provider agreements under Medicare:

- Hospitals,
- Skilled nursing facilities (SNFs),
- Home health agencies (HHAs),
- Clinics, rehabilitation agencies, and public health agencies,
- Comprehensive outpatient rehabilitation facilities (CORFs),
- Hospices,
- Critical access hospitals (CAHs), and
- Community mental health centers (CMHCs).

Clinics, rehabilitation agencies, and public health agencies may enter into provider agreements only for furnishing outpatient therapy services as defined in section 10 above. CMHCs may enter into provider agreements only to furnish partial hospitalization *or intensive outpatient* services.

The term "provider agreement" is defined in 42 CFR 489.3 as an agreement between CMS and one of these providers specified in this section to provide services and to comply with the requirements of section 1866 of the Act.

A provider which has executed an agreement becomes qualified to participate after the agreement is accepted. When the agreement is made retroactive, the provider must comply with the terms of the agreement and the provisions of title XVIII and regulations issued thereunder as of the retroactive date. For payment to be made to the provider for covered items and services it

furnishes on or after the effective date of the agreement, the provider must have a record keeping capability sufficient to determine the costs of services furnished to Medicare beneficiaries.

Provider agreements require the providers to comply with regulations. Therefore, new provider agreements are not made when regulations change.

Providers as defined in this section may also function as suppliers and bill the program for other services provided as suppliers if they meet the applicable requirements for supplying the specific service.