Physician Self-Referral Law

Annual Update to the List of CPT/HCPCS Codes Effective January 1, 2025

I. Background

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law: (1) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless the requirements of an applicable exception are satisfied; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for any improperly referred designated health services. The physician self-referral regulations are found at 42 CFR Part 411 Subpart J. In § 411.351, we specify that the entire scope of four categories of designated health services is defined in a list of CPT/HCPCS codes (the Code List), which is updated annually to account for changes in the most recent CPT and HCPCS Level II publications. The categories defined and updated in this manner are:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.

The Code List also identifies those items and services that may qualify for either of the following two exceptions to the physician self-referral prohibitions:

- EPO and other dialysis-related drugs (§ 411.355(g)).
- Preventive screening tests and vaccines (§ 411.355(h)).

Beginning with the January 1, 2023 Code List, we publish the Code List solely on the CMS website. (See the CY 2022 Physician Fee Schedule (PFS) final rule for further information (86 FR 65356 through 65357)).

The definition of "designated health services" at § 411.351 excludes services for which payment is made by Medicare as part of a composite rate (unless the services are specifically included in the statutory or regulatory lists of items and services that are designated health services and are themselves payable through a composite rate, such as home health and inpatient and outpatient hospital services). Medicare makes payment for most end-stage renal disease (ESRD) services as part of a composite rate. ESRD-related oral-only drugs, which are drugs or biological products with no injectable functional equivalents or other forms of administration other than an oral form, were scheduled to be paid under the ESRD prospective payment system (ESRD PPS) beginning January 1, 2014 (75 FR 49044). However, there have been several delays of the implementation of payment of these drugs under the ESRD PPS. On December 19, 2014, section 204 of the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295) was enacted and delayed the inclusion of these oral-only drugs or biological

products furnished in or by an ESRD facility are included in the composite rate payment and, thus, are not designated health services (89 FR 89084).

<u>COVID-19</u>

The COVID-19 public health emergency (PHE) ended May 11, 2023. The U.S. Government is no longer purchasing COVID-19 vaccines and the CDC COVID-19 Vaccination Program has ended. COVID-19 vaccines are now payable by Medicare and therefore are designated health services. On the CY 2025 Code List, COVID-19 vaccines remain eligible for the exception for preventive screening tests and vaccines at § 411.355(h). Note that the inclusion of CPT code 90749 on the Code List as eligible for this exception is not intended and should not be considered to direct or approve the use of CPT code 90749 for the identification and billing of any COVID-19 vaccine. To the extent that CMS pays for COVID-19 monoclonal antibody products for post-exposure prophylaxis or treatment of COVID-19 as "vaccines" under the Medicare Part B vaccine benefit in section 1861(s)(10) of the Act, the products are eligible for the exception for the exception for preventive screening tests and vaccines at § 411.355(h).

II. Instructions for Submitting Comments on CY 2025 Code List.

We will consider comments regarding the codes listed in the tables in section IV below. To submit a comment, go to <u>www.regulations.gov</u> and enter the docket number "CMS-2024-0301" in the search field. Select the "Comment" button and follow the instructions. To be considered, comments must be received on or before December 26, 2024. Comments will be made public, so submitters should not include any confidential or personal information. Please note that we will not consider any comment that advocates a substantive change to any of the designated health services defined in § 411.351.

III. Revisions Effective for CY 2025

The Code List effective January 1, 2025, is available on our website at <u>https://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral/list_of_codes</u>. Additions and deletions to the Code List conform it to the most recent publications of CPT and HCPCS Level II and to changes in Medicare coverage policy and payment status. In the charts below, we identify the additions and deletions, respectively, that will be effective January 1, 2025. The charts below also include the additions and deletions to the list of codes used to identify the items and services that may qualify for the exceptions at § 411.355(g) (regarding dialysis-related outpatient prescription drugs furnished in or by an ESRD facility) and § 411.355(h) (regarding preventive screening tests and vaccines).

Additions to the Physician Self-Referral List of CPT ¹ /HCPCS	Codes
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(INCL	UDE codes for all clinical laboratory services in the 80000 series)
	IPONENT COLLECTION SERVICES IN THE 80000 SERIES THAT ARE
I	EXCLUDED FROM CLINICAL LABORATORY SERVICES
{No Additions}	
OTHER COI	DES NOT IN 80000 SERIES INCLUDED IN CLINICAL LABORATORY
	SERVICES
0020M	Onc cns alys 30000 dna loci
0898T	N-invas prst8 cancer est map
0248U	Onc sphrd cell cul 12 rx pnl
0439U	Crd chd dna alys 5 snp 3 dna
0440U	Crd chd dna alys 10 snp 6dna
0441U	Nfct ds bct fngl/viral semiq
0442U	Nfct ds respir nfctj mxa&crp
0443U	Neurflmnt lt chn ultrsens ia
0444U	Onc sld orgn neo tgsap 361
0445U	Abeta42 & ptau181 eclia csf
0446U	Ai ds sle alys 10 cytokine
0447U	Ai ds sle alys 11 cytokine
0449U	Car scr sev inh cond 5 genes
0450U	Onc mm lc-ms/ms monoc p-prtn
0451U	Onc mm lc-ms/ms pep ion quan
0452U	Onc bldr mthyl penk lte-qmsp
0453U	One elret ca efdna qper asy
0454U	Rare ds id opt genome mapg
0455U	Nfct agt sti mult amp prb ur
0457U	Pfas 9 cmpnd lcms/ms pls/sr
0458U	Onc brst ca s100 a8&a9 elisa
0459U	Abeta42 & ttau eclia csf
0460U	Onc whl bld/bucc rtpcr 24gen
0461U	Onc rxgenom alys rtpcr 24gen
0462U	Melatonin lvl tst slp std7/9
0463U	Onc crvx mrna genxprsn 14bmk
0464U	Onc clrct scr qrtsa dna mrk
0465U	Onc urthl carc dna qmsp 2gen
0466U	Crd cad dna gwas 564856 snp
0467U	Onc bldr dna ngs 60gen&aneup
0468U	Hep nash mir34a5p a2m ykl40

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0469U	Rare ds whl gen seq ftl samp
04090 0470U	Onc orop detcj mrd 8 dna hpv
04700 0471U	One circ ca 35 vrn kras&nras
04710 0472U	Ca vi psp&sp1 antb sjogren
04720 0473U	Onc sld tum bld/slv 648 gene
04730 0474U	Hered pan ca gsap 88gene ngs
04740 0475U	Hered prst8 ca gsap 23 genes
04730 0476U	
	Rx metab psyc 14gen&cyp2d6
0477U	Rx metab psy 14&cyp2d6 gn-rx
0478U	One nsele dna&rna dper 9gens
0479U	Tau phosphorylated ptau217
0480U	Nfct ds csf metag ngs alys
0481U	Idh1 idh2&tert promoter ngs
0482U	Ob pe biochem asy sflt1&plgf
0483U	Nfct ds ng gyra s91f pt mut
0484U	Nfct ds mgen 23s rrna pt mut
0485U	Onc sol tum cfdna&rna ngs gm
0486U	Onc pan sol tum ngs cfctdna
0487U	Onc sol tum cfcdna tgsap 84
0488U	Ob fetal ag nipt cfdna alys
0489U	Ob sgnipt cfdna seq alys 1+
0490U	Onc cutan/uveal mlnma cd146
0491U	Onc sol tum ctc slct er prtn
0492U	Onc sol tum ctc slctn pd-l1
0493U	Trnspl med quan dd-cfdna ngs
0494U	Rbc ag ftl rhd gene alys ngs
0495U	Onc prst8 alys crcg plsm prt
0496U	Onc clrct cfdna 8/7 genes
0497U	Onc prst8 mrna rt-pcr 6genes
0498U	Onc clrct ngs mut detc 43gen
0499U	Onc clrct&lng dna ngs 8genes
0500U	Autoinflam ds vexas synd dna
0501U	Onc clrc bld quan meas cfdna
0502U	Hpv e6/e7 mrk hirsk typ crv
0503U	Neuro alz ds βamylτ prtn
0504U	Nfct ds uti id 17 path orgs
0505U	Nfct ds vag infctj id 32orgs
0506U	Gi barretts esophgl cell 89
0507U	Onc ovr dna whole gen w/5hmc
0508U	Trnsplj med ddcfdna 40 snps
0509U	Trnsplj med ddcfdna<12 snps
0510U	
	One pnerte ca alg alys 16gen

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93896	Vsrctv std tcd icr art compl
93897	Emboli detcj wo iv mbubb njx
93898	Ven-artl shunt det mbubb njx
A9506	Tc-99m graphite crucible
A9610	Xe129 xenon, diagnostic
C8001	3D anat seg imaging preop
	RADIATION THERAPY SERVICES AND SUPPLIES
0947T	Mrgfus strtctc bl-br disrpj
51020	Cystotomy/cystostomy w/fulg [only when cystotomy/cystostomy includes
	insertion of radioactive material]
61715	Mrgfus strtctc ablt trgt icr
G0562	Complex simulation w/pet-ct
G0563	Sbrt w/positron emission del
]	DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
{No Additions}	
	PREVENTIVE SCREENING TESTS AND VACCINES
74263	Ct colonography screening
90637	Vacc qirv mrna 30mcg/.5ml im
90638	Vacc qirv mrna 60mcg/.5ml im
90684	Pcv21 vaccine im
90695	H5n8 vacc drv cll cul adj im
Q0224	Inj, pemivibart, 4500 mg

Deletions from the Physician Self-Referral List of CPT²/HCPCS Codes

	CLINICAL LABORATORY SERVICES
BLOOD CON	MPONENT COLLECTION SERVICES IN THE 80000 SERIES THAT ARE
	EXCLUDED FROM CLINICAL LABORATORY SERVICES
{No Deletions}	
OTHER CO	DES NOT IN 80000 SERIES INCLUDED IN CLINICAL LABORATORY
	SERVICES
0204U	One thyr mrna xprsn alys 593
0346U	Beta amyl ab40&ab42 lc-ms/ms
0352U	Nfct ds bv&vaginitis amp prb
0353U	Iadna chlmyd&gonorr amp prb
0354U	Hpv hi rsk qual mrna e6/e7

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0380U	Rx metb advrs trgt sq aly 20
0396U	Ob preimpltj tst 300000 dna
0416U	Iadna gu pthgn 20bct&fng org
0428U	Onc brst ctdna alys 56/> gen
PHYSICAL	THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH- LANGUAGE PATHOLOGY SERVICES
96003	Dynamic fine wire emg
	RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
93890	Tcd vasoreactivity study
C9150	Xe129 xenon, diagnostic
C9734	U/s trtmt, not leiomyomata
C9786	Echo cad for hf preserved ef
	RADIATION THERAPY SERVICES AND SUPPLIES
64625	Rf abltj nrv nrvtg si jt
64625 C9794	Rf abltj nrv nrvtg si jt Complex simulation w/pet-ct
	Rf abltj nrv nrvtg si jt
C9794 C9795	Rf abltj nrv nrvtg si jt Complex simulation w/pet-ct Sbrt w/positron emission del DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
C9794	Rf abltj nrv nrvtg si jt Complex simulation w/pet-ct Sbrt w/positron emission del DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
C9794 C9795	Rf abltj nrv nrvtg si jt Complex simulation w/pet-ct Sbrt w/positron emission del DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
C9794 C9795	Rf abltj nrv nrvtg si jt Complex simulation w/pet-ct Sbrt w/positron emission del DRUGS USED BY PATIENTS UNDERGOING DIALYSIS }
C9794 C9795 {No Deletions	Rf abltj nrv nrvtg si jt Complex simulation w/pet-ct Sbrt w/positron emission del DRUGS USED BY PATIENTS UNDERGOING DIALYSIS } PREVENTIVE SCREENING TESTS AND VACCINES
C9794 C9795 {No Deletions 90630	Rf abltj nrv nrvtg si jt Complex simulation w/pet-ct Sbrt w/positron emission del DRUGS USED BY PATIENTS UNDERGOING DIALYSIS } PREVENTIVE SCREENING TESTS AND VACCINES Flu vacc iiv4 no preserv id
C9794 C9795 {No Deletions 90630 90654	Rf abltj nrv nrvtg si jt Complex simulation w/pet-ct Sbrt w/positron emission del DRUGS USED BY PATIENTS UNDERGOING DIALYSIS } PREVENTIVE SCREENING TESTS AND VACCINES Flu vacc iiv4 no preserv id Flu vacc iiv3 no preserv id
C9794 C9795 {No Deletions 90630 90654 91302	Rf abltj nrv nrvtg si jt Complex simulation w/pet-ct Sbrt w/positron emission del DRUGS USED BY PATIENTS UNDERGOING DIALYSIS } PREVENTIVE SCREENING TESTS AND VACCINES Flu vacc iiv4 no preserv id Flu vacc iiv3 no preserv id Sarscov2 vac 5x10^10vp/.5mlim