

512.397 ETC Model Medicare program waivers.

The following provisions are waived solely for purposes of testing the ETC Model.

(a)(1) Medicare payment waivers. CMS waives the requirements of sections 1833(a), 1833(b), 1848(a)(1), 1881(b), and 1881(h)(1)(A) of the Act only to the extent necessary to make the payment adjustments under the ETC Model described in this subpart.

(2) Beneficiary cost sharing. The payment adjustments under the ETC Model described in this subpart do not affect the beneficiary cost-sharing amounts for Part B services furnished by ETC Participants under the ETC Model.

(b) CMS waives the following requirements of title XVIII of the Act solely for purposes of testing the ETC Model:

(1) CMS waives the requirement under section 1861(ggg)(2)(A)(i) of the Act and § 410.48(a) and (c)(2)(i) of this chapter that only doctors, physician assistants, nurse practitioners, and clinical nurse specialists can furnish KDE services to allow KDE services to be provided by clinical staff under the direction of and incident to the services of the Managing Clinician who is an ETC Participant. The KDE benefit must be furnished and billed by a Physician, clinical nurse specialist, licensed social worker, nurse practitioner, physician assistant, registered dietician/nutrition professional, or a clinic/group practice.

(2) CMS waives the requirement that the KDE is covered only for Stage IV chronic kidney disease (CKD) patients under section 1861(ggg)(1)(A) of the Act and § 410.48(b)(1) of this chapter to permit beneficiaries diagnosed with CKD Stage V or within the first 6 months of starting dialysis to receive the KDE benefit.

(3) CMS waives the requirement that the content of the KDE sessions include the management of co-morbidities, including delaying the need for dialysis, under § 410.48(d)(1) of this chapter when such services are furnished to beneficiaries with CKD Stage V or ESRD, unless such content is relevant for the beneficiary.

(4) CMS waives the requirement that an outcomes assessment designed to measure beneficiary knowledge about chronic kidney disease and its treatment be performed by a qualified clinician as part of one of the KDE sessions under § 410.48(d)(5)(iii) of this chapter, provided that such outcomes assessment is performed within 1 month of the final KDE session by qualified staff.