

42 C.F.R. § 414.701

Purpose.

This subpart implements section 1842(o) of the Act by specifying the methodology for determining the payment allowance limit for drugs and biologicals covered under Part B of Title XVIII of the Act (hereafter in this subpart referred to as the “program”) that are not paid on a cost or prospective payment system basis. Examples of drugs that are subject to the rules contained in this subpart are: Drugs furnished incident to a physician's service; durable medical equipment (DME) drugs; separately billable drugs at independent dialysis facilities not under the ESRD composite rate; statutorily covered drugs, for example, influenza, pneumococcal, hepatitis, and COVID-19 vaccines, antigens, hemophilia blood clotting factor, immunosuppressive drugs and certain oral anti-cancer drugs.

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