



Comments of the American College of Clinical Pharmacy

**Statement to Centers for Medicare & Medicaid
Services (CMS), Department of Health and Human
Services (HHS)**

**Essential Health Benefits (EHB) under the Patient
Protection and Affordable Care Act (the Affordable
Care Act or ACA)**

January 31, 2023

Submitted electronically at: <https://www.regulations.gov>



**Office of Government and Professional Affairs
1455 Pennsylvania Ave., NW
Suite 400
Washington, DC 20004
(202) 621-1820
www.accp.com**

The American College of Clinical Pharmacy (ACCP) appreciates the opportunity to provide the following statement in response to the December 2, 2022, request for information (RFI) from the Centers for Medicare & Medicaid Services (CMS) soliciting public comment on issues related to the Essential Health Benefits (EHB) under the Patient Protection and Affordable Care Act (ACA).

ACCP is a professional and scientific society that provides leadership, education, advocacy, and resources enabling clinical pharmacists to achieve excellence in patient care practice and research. ACCP's membership is composed of more than 18,000 clinical pharmacists, residents, fellows, students, scientists, educators and others who are committed to excellence in clinical pharmacy practice and evidence-based pharmacotherapy.

ACCP's members practice in a variety of team-based settings, including ambulatory care environments, hospitals, colleges of pharmacy and medicine, the pharmaceutical industry, government and long-term care facilities, and managed care organizations. Our focus is the optimization of medication regimens to achieve patient-centered therapeutic goals.

Addressing Gaps in Coverage: Achieving Medication Optimization

The Medicare Part D drug benefit successfully expanded Medicare to include prescription medications in the early 2000s. The Medicare Part B program has long covered a limited number of physician-administered medications. However, Medicare has never had, and still lacks, a meaningful benefit to ensure that these expensive and complex prescription medications truly provide optimal value in improving patients' lives. We hope the time for that to change is now.

Coverage of prescription drugs has always been included as part of the EHB package. However, it is our contention that just as important as medication access and affordability -- if not more important -- is maximizing the effectiveness and the value of the medication therapy prescribed. Comprehensive medication management (CMM) delivered by clinical pharmacists is the most effective means of achieving this critically important goal.

CMM is a direct patient care service, provided by clinical pharmacists working as formal members of the patient's health care team that has been demonstrated to significantly improve clinical outcomes and enhance the safety of medication use by patients.

CMM is a well-established standard of care in our nation's leading private sector health systems, including Geisinger,¹ Kaiser Permanente,² Mayo Clinic,³ and Johns Hopkins.⁴ Nationally, VA clinical pharmacy specialists (CPS) hold scopes of practices that confer medication prescriptive authority and the responsibility to modify, start, stop and/or continue medications as per guideline recommendations, collaborative practice agreements, and the CPS' clinical judgment.

¹ Jones LK, Greskovic G, Grassi DM, Graham J, Sun H, Gionfriddo MR, Murray MF, Manickam K, Nathanson DC, Wright EA, Evans MA. Medication therapy disease management: Geisinger's approach to population health management. *Am J Health Syst Pharm.* 2017 Sep 15;74(18):1422-1435. doi: 10.2146/ajhp161061. PMID: 28887344.

² Witt, Daniel. (2008). The Kaiser Permanente Colorado Clinical Pharmacy Anticoagulation Service as a model of modern anticoagulant care. *Thrombosis research.* 123 Suppl 1. S36-41. 10.1016/j.thromres.2008.08.004.

³ Peinovich M, Darracott R, Dow J. Developing pharmacy services in a home hospital program: The Mayo Clinic experience. *Am J Health Syst Pharm.* 2022 Oct 21;79(21):1925-1928. doi: 10.1093/ajhp/zxac200. PMID: 35896358; PMCID: PMC9384588.

⁴ Maryland Primary Care Program (MDPDP): Participating Care Transformation Organizations (CTO) List. [Accessed 1/25/2023.](#)

CPS also perform associated physical assessments, order lab tests, and initiate consults for other services.

In addition, the Veterans Health Care system has systematically integrated CPS into Patient-Aligned Care Teams (PACT) to significantly improve patient outcomes through the delivery of CMM for a range of chronic conditions.⁵

Coverage of Prescription Drugs as EHB: Optimizing Specialty Drug Use

ACCP believes that in order to achieve a health care system that delivers better care, smarter spending, and healthier people and communities, it is vital to establish a truly team-based, patient-centered approach to health care consistent with evolving delivery and payment models currently available under private and commercial health plans.

It is estimated that \$528 billion dollars a year⁶, equivalent to 16 percent of total health care spending, is consumed due to inappropriate or otherwise ineffective medication use. Given the central role that medications play in care and treatment of chronic conditions, combined with the continuing growth in the range, complexity and cost of medications – and greater understanding of the genetic and physiologic differences in how people respond to their medications – the nation’s health care system consistently fails to deliver on the full promise medications can offer.

The rapidly increasing cost of many existing and newly approved drugs is a major and growing concern to patients, the American public, commercial and federal payers, and health policy economists and regulators.

Specialty prescription drugs can be defined as a prescription drug with a “total average prescription cost greater than \$1,000 per prescription; or a total average cost per day of therapy greater than \$33 per day.”⁷ The Centers for Medicare & Medicaid Services (CMS) defines specialty drugs as pharmaceuticals costing \$600 or more per month.⁸

ACCP believes that a patient-centered, team-based, and evidence-driven approach to CMM must be paired with emerging value-based pricing approaches to better ensure that the rational and economical use of specialty drugs is optimized both for patients and for the health care system. CMM, applied through standardized clinical practice processes is a cornerstone of interprofessional, patient-centered care that can better ensure optimized, economical specialty drug use.

Implementation of Pharmacogenomics (PGx) to Achieve Medication Optimization

⁵ GTMRx Institute CMM In Practice Case Example: William S. Middleton Memorial Veterans Hospital, Madison, WI. [Accessed 1/25/23](#)

⁶ Watanabe, J., McInnis, T., & Hirsch, J. (2018). Cost of Prescription Drug-Related Morbidity and Mortality. *The Annals of pharmacotherapy*, 52(9), 829-837. <http://dx.doi.org/10.1177/1060028018765159> Retrieved from <https://escholarship.org/uc/item/3n76n4z6>

⁷ Schondelmeyer SW, Purvis L. Rx price watch report. Trends in retail prices of specialty prescription drugs widely used by older Americans, 2006 to 2013 [research report], 2015. Available from www.aarp.org/content/dam/aarp/ppi/2015/rx-price-watch-specialty-prescription-drug-prices-continue-to-climb-final.pdf.

⁸ Centers for Medicare & Medicaid Services (CMS). Medicarepart D specialty tier [guidance document], 2014. Available from www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/SpecialtyTierMethodology.pdf.

Pharmacogenomics (PGx) allows clinicians to assess how a patient's genetic profile determines their responses to specific medications. Appropriate diagnosis and access to advanced diagnostics like PGx testing is essential to ensure safe and effective therapy for each patient. When applied as a component of CMM, PGx ensures that a patient's medications are individually assessed to determine that each is indicated, effective, consistent with patient expectations, and safe, in view of the comorbidities present, other concurrent medications, and the patient's ability to adhere to the prescribed regimen.

When integrated into CMM, PGx testing allows for targeted treatment decisions based on the unique characteristics of the patient's unique genetic profile. The integration of PGx within CMM reduces costs, improves outcomes and access to care, and enhances patient and provider quality of life and satisfaction. To ensure medication optimization, pharmacogenomics (PGx) should be integrated into CMM.

About Clinical Pharmacists

Clinical pharmacists are practitioners who provide CMM and related care for patients in all health care settings. They are licensed pharmacists with specialized, advanced education and training who possess the clinical competencies necessary to practice in team-based, direct patient care environments. Accredited residency training or equivalent post-licensure experience is necessary for entry into direct patient care practice. Board certification is also expected once the clinical pharmacist meets the eligibility criteria specified by the Board of Pharmacy Specialties (BPS). In providing CMM, they establish a valid collaborative drug therapy management (CDTM) agreement with the patient's provider or are formally granted clinical privileges within a health care practice/institution.

Summary

We thank you for the opportunity to provide input on the EHB package to address changing public health concerns and to integrate coverage for new innovations in health care. As part of this effort, we urge you to utilize the unique contributions of clinical pharmacists in the area of medication optimization.

ACCP is dedicated to advancing a quality-focused, patient-centered, team-based improvement in health care delivery that (1) helps assure medication optimization, (2) enhances patient safety (3) promotes value-based rather than volume-based care and (4) contributes to greater affordability, sustainability, and equity for our nation's health delivery systems program. We look forward to working with you to help achieve these goals.