U.S. Department of Veterans Affairs
Veterans Health Administration
Pharmacy Benefits Management (PBM) Services
Clinical Pharmacy Practice Office (CPPO)

Clinical Pharmacist Practitioner (CPP) Role in Oncology
June 2021

EXECUTIVE SUMMARY:

This Fact Sheet highlights the critical role of the Oncology Clinical Pharmacist Practitioner (CPP) in the provision of comprehensive medication management (CMM) services in the cancer care continuum and how full integration of the CPP in team-based settings can significantly improve oncology access issues within the VA.

Key Highlights

- The CPP is an integral team member providing CMM expertise to reduce medication-related problems, errors, and morbidity in our Veterans and as part of the Oncology team in delivering evidence-based, safe, efficient, and cost-effective care.
- The Oncology CPP functions autonomously under a scope of practice to perform comprehensive medication management (CMM) as described in VHA Handbook 1108.11 Clinical Pharmacy Service.
- The CPP plays a critical role in the creation, maintenance, and education of technology utilized to prescribe and administer high risk medications.
- Optimization of the CPP role allows other Oncology providers to address acute and urgent needs of the oncology patient.
    - There are over 130 CPPs within the VA, many with a global scope of practice for CMM in oncology. During FY20, there were 67,578 encounters by an Oncology CPP, a 27% increase since FY18.
    - The CPP is a well-trained workforce. Many have completed general PGY1 residency training and PGY-2 oncology residency training. In addition, a significant number have obtained advanced Board Certification in Oncology Pharmacy (BCOP).
    - In 2019, 184 pharmacists graduated from 105 PGY-2 Oncology pharmacy residency training programs throughout the U.S. and were ready for hire in July. These numbers have grown exponentially over the past 5 years and are estimated to continue based on demand.
    - Within the VA, 5 facilities offer PGY2 oncology residencies training 6 residents per year.
- Significant shortages of Oncology practitioners exist across the nation and VA. Facilities have a significant opportunity to re-deploy or add additional trained CPP to help bridge this gap. Appropriate allocation of resources to CPP allows for an additional avenue to addressing oncology prescriber staffing needs at facilities.

BACKGROUND

A workforce forecast projected the demand for oncology services to grow by 48% by 2020 and oncologist supply only to increase by 20%, indicating an expected shortage of Oncology providers.[1] Factors contributing to the increased demand include an aging population, growing number of therapies that

extend life, increasing complexity of therapy requiring more frequent monitoring and visits, and growing cancer survivor rate which contributes to overall prevalence of cancer.[1] CPPs are highly qualified advanced practice providers that can be instrumental in addressing the workforce shortage, issues arising from the growing demand for oncology services, and increasing access for oncological care for the Veteran population.[2-4] CPP share diverse roles in cancer therapy management, including outpatient and inpatient medication management, sterile compounding of anticancer treatments, formulary management including prior authorization adjudication of specialty medications for risk mitigation when appropriate, investigational drug services, and informatics.[2-6] CPP are an integral part of the oncology team working to reduce medication-related problems, medication errors, and overall drug-related morbidity.[5,7] Oncology pharmacy services have been valued with high satisfaction from both patients and physicians.[5,7,8] The economic benefit of CPP interventions and process improvement projects in Oncology has also been shown in several studies.[5,8] Therefore, clinical pharmacy services undeniably improve the quality, safety, and access to care for patients with cancer.

At the VA, CPP are advanced practice providers that have specialized training and practice under a scope of practice approved by the executive committee of the medical center. [3] This allows the CPP to practice CMM in different settings and can be utilized as a way to bridge gaps in oncology care. The CPP has expertise and specialized training in antineoplastic agent selection, management, monitoring, and preparation/handling/dispensing, which makes them a highly valued and necessary part of oncology care in a variety of practice settings.

ROLE OF THE ONCOLOGY CLINICAL PHARMACY SPECIALIST

The CPP serves in a variety of key roles to improve patient-centered care and oncology medication outcomes by supporting the needs of the oncology team, patients and caregivers.

The CPP is an integral part of the oncology team, advocating for the patient to assure safe medication practices are delivered. The Oncology CPP focuses on cancer therapy education, toxicity monitoring, and supportive care management. Often the CPP functions independently under a scope of practice which includes medication prescriptive authority as well as core elements outlined in VHA Handbook 1108.11, Clinical Pharmacy Services . These examples should be considered when developing roles for Oncology CPP at your facility, based on facility needs and priorities.

The main role of the CPP is in the provision of oncology comprehensive medication management (CMM). These activities focus on treatment appropriateness, effectiveness, safety, cost awareness, and adherence to treatments for oncology but also management of adverse events, and concomitant disease states. The monitoring and evaluation of oral anticancer therapies has been identified as a potential area of impact by the CPP. Within their scope of practice, most CPPs order lab monitoring as needed. The CPP can identify toxicities early, thereby preventing the dispensing of expensive medication when it may require dose adjustment or discontinuation. The CPP ensures the patient receives appropriate supportive care, lab monitoring, and follow up to optimize each anticancer therapy by working collaboratively with the Oncology provider. Additionally, the CPP would seek consultation with the oncologist or appropriate provider for advanced patient care management beyond the CPP scope of practice.

The Oncology CPP is an advance practice provider who is a highly trained medication management expert, providing CMM services, in accordance with their individualized scope of practice with prescriptive authority as outlined in the VHA Handbook 1108.11, Clinical Pharmacy Services. CMM services include oncology treatments and supportive care medications, as well oral or intravenous anticancer therapies,

depending on facility needs. This may also include renewals at same dose and dose adjustments. However, due to guidelines for safe ordering/administration of anticancer therapies, the CPP often serves as one "check" in the system of multiple "checks" of chemotherapy ordering, therefore, may not be the primary prescriber.

In many circumstances, the CPP works collaboratively with the oncology provider by providing therapeutic recommendations for safe and effective anticancer therapy for individual Veterans. The CPP may take into account performance status, organ function, previous anticancer therapies, cost/formulary status, genetic testing, and evaluation of available literature when making recommendations. The CPP serves as a resource for all members of the oncology team on evidence-based pharmacological treatment options.

The CPP is often heavily involved in developing and maintaining essential anticancer therapy ordering systems, whether electronic health record (EHR) based, paper based, or secondary computerized order entry system (e.g., Vista Chemotherapy Manager). The specialized knowledge in complex anticancer therapy regimens as well as knowledge in safe ordering practices, make the involvement of the CPP in this area essential.

Comprehensive Medication Management functions:

- Assess and develop selection of evidence-based and therapeutically appropriate anticancer therapies based on Veteran diagnosis, performance status, organ function, disease staging and pertinent pharmacogenomic status
- Develop and implement evidence based anticancer order set to standardize therapy approaches to ensure safety, efficacy and completeness of anticancer treatment protocols. Assess, select and initiate primary and secondary supportive care elements for inclusion in anticancer order sets based on anticancer protocol risk
    - Primary supportive care therapies for anticancer treatment include but are not limited to addition of growth factor support based on regimen risk of febrile neutropenia, infection prophylaxis, prevention and treatment of chemotherapy induced nausea/vomiting, diarrhea/constipation, anticipated skin toxicities, therapy induced electrolyte imbalances, risk of hypersensitivity reactions, drug interactions, thrombosis prevention, etc.
- Assess, monitor and manage anticancer therapy adverse drug reactions or toxicities including but not limited to hypersensitivity reactions, refractory nausea/vomiting, therapy induced cytopenias (including neutropenia and anemia), infection, QT prolongation, immune-mediated toxicities, organ dysfunction, diarrhea/constipation, dermatologic reactions, fatigue, nutritional deficiencies, and drug interactions
- Initiate, monitor, modify and discontinue medications as part of management of clinical effectiveness and toxicity
- Review primary literature resources and appropriate guidelines (e.g., NCCN, ASCO) when evaluating, recommending or implementing anticancer therapy and supportive care
- Recommend and perform targeted lab monitoring as clinically indicated
- Serve as a SME to provide input on issues related to VA formulary, Clinical Pathway and guideline concordance
- Provide patient education for oral and intravenous anticancer therapies
- Increase access to clinical services by providing comprehensive medication management to Veterans receiving oral anticancer therapies via multiple modalities (e.g., Face to Face appointments, telephone, VVC)

- Provide education as the medication expert to assist with clinical training programs including medical residents, pharmacy residents and interns, hematology/oncology fellows as well as interprofessional education of other Oncology team members
- Serve as a SME to oncology informatics as needed, including VCM, BCMA, CPRS.
- Facilitate timely and judicious procurement of anticancer therapies
- Monitor and assist with necessary therapy changes during times of critical drug or supply shortages
- Provide consultation as needed for anticancer compounding with regards to USP Chapters <795>, <797> and <800> compliance, VHA Directive 1108.12, Management and Monitoring of Pharmaceutical Compounded Sterile Preparations, The Joint Commission accreditation, FDA requirements and NIOSH requirements.

CURRENT ASSESSMENT OF CLINICAL PHARMACY ONCOLOGY PRACTICE

Nationwide, there are currently 4,775 CPP with a scope of practice caring for Veterans in both inpatient and outpatient settings. Among those, over 130 are dedicated in the Oncology/Hematology area. Of the CPPs identified many have a scope of practice at their practice site, have completed PGY-1 and PGY-2 training. In addition, a significant number have successfully obtained advanced board certification recognized as BCOP. Many of these CPPs are also dedicated to training future CPPs in this specialty area. Within the VA Health Care System there are five VA's with a PGY2 Hematology/Oncology residency, which graduate six PGY2 Hematology/Oncology residents annually.

In November 2019, an electronic survey was distributed to members of the CPPO Subject Matter Expert (SME) Oncology workgroup representing 18 VA facilities. Results were collected and evaluated from 16 facilities. On average, 1.74 full time employee (FTE) pharmacists are assigned to Oncology/Hematology per facility. Of those, an average of 1.38 FTEs are BCOP. The CPP is involved in several different areas including pharmacist oral chemotherapy clinic, ambulatory infusion clinics, inpatient Oncology/Hematology, and inpatient infusions for non-Hematology/Oncology patients. Majority of the sites do not have clinical Oncology/Hematology pharmacy technician support.

In the outpatient setting, the CPPs are involved in prescribing oral and parenteral anti-neoplastic agents, supportive care management and controlled substance prescriptions. These may be accomplished through a variety or modalities including face-to-face visits, phone clinics, or VA Video Connect (VVC) follow ups. In the inpatient setting, the CPP is primarily involved as part of a consult service to provide care for Veterans receiving chemotherapy. Additionally, in some facilities, the CPP provides continual inpatient coverage. Scopes of practice for outpatient or inpatient management often include ordering of basic labs, tumor markers, and imaging studies such as PET/CT and x-ray.

In FY20, there were 67,578 Oncology/Hematology patient care encounters. There has been a continued increase in Oncology/Hematology encounters over time as shown in Figure 1. From these encounters, a total of 141,009 interventions were made during FY20 (Figure 2). The most common types of interventions made during FY20 are described in Figure 3. Additionally, with updated information, it is noted that CPP encounters continue to increase through the 3rd quarter of FY2020 (Figure 4).

Figure 1. Oncology/Hematology Encounters by a CPP for FY13-FY20

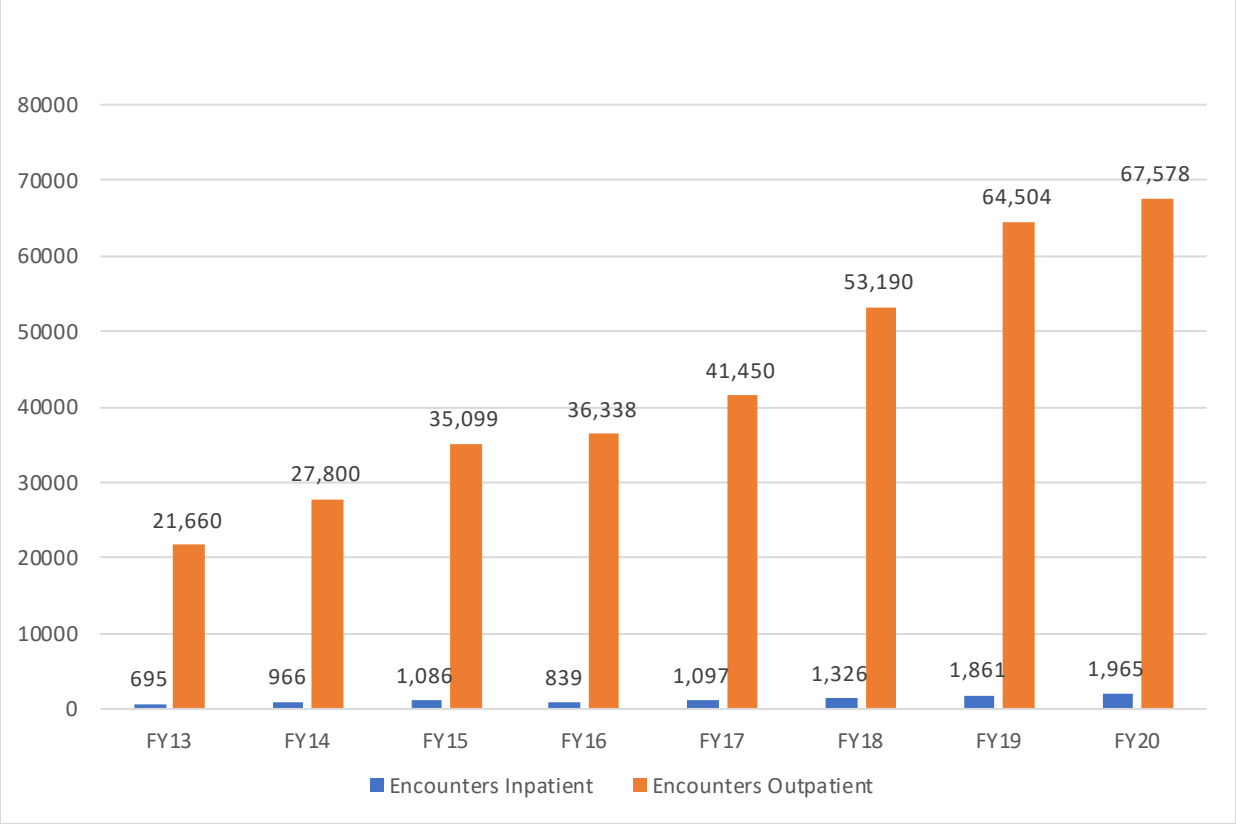


Figure 2. Oncology/Hematology PhARMD Interventions by a CPP for FY13-FY20

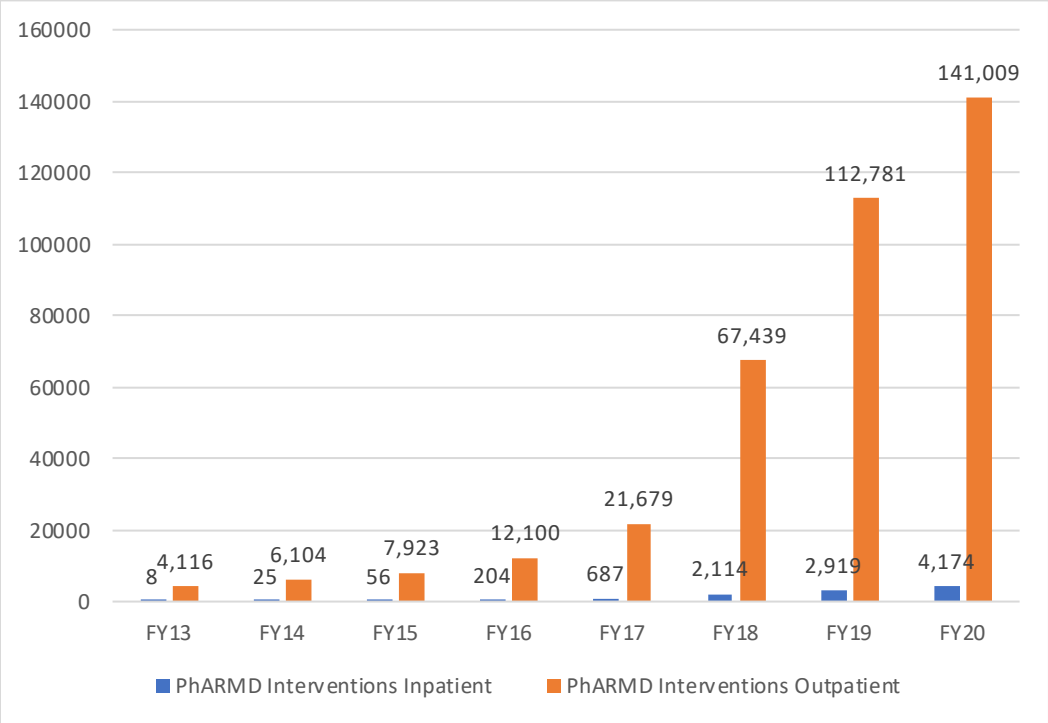


Figure 3. Top 15 PhARMD Oncology/Hematology Interventions FY20

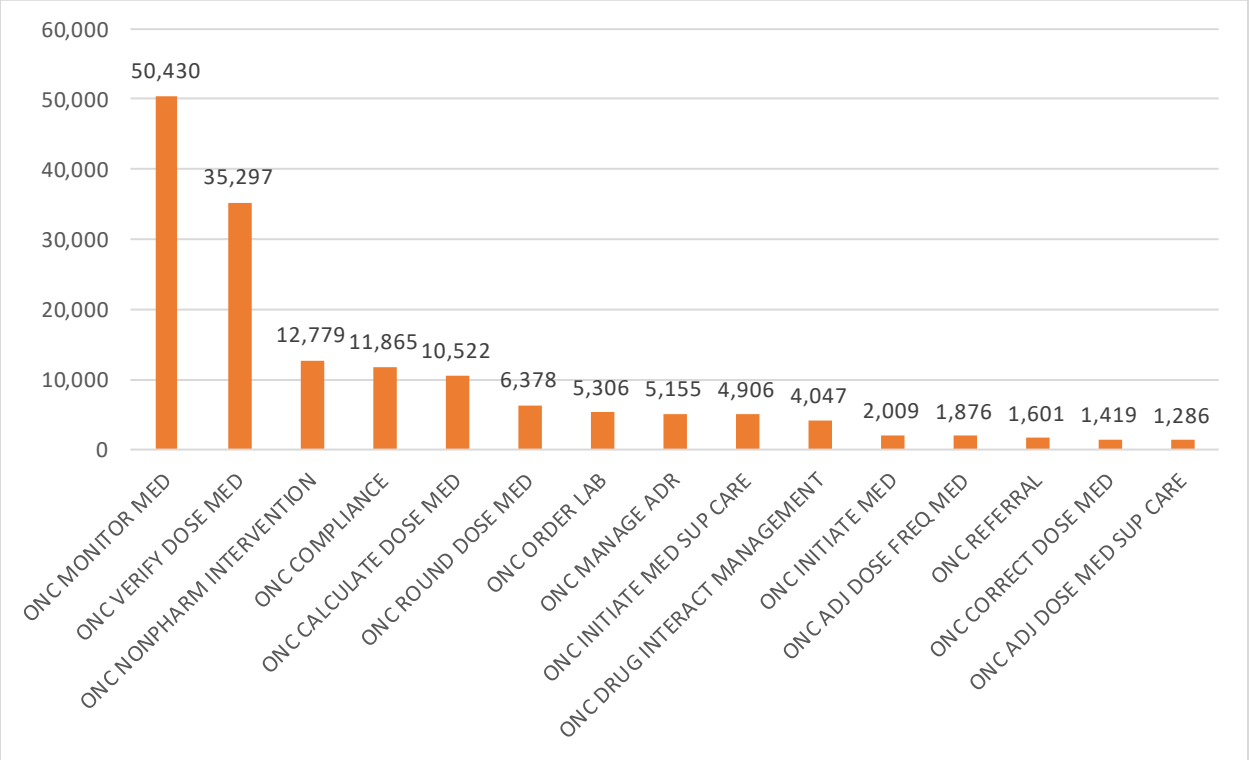
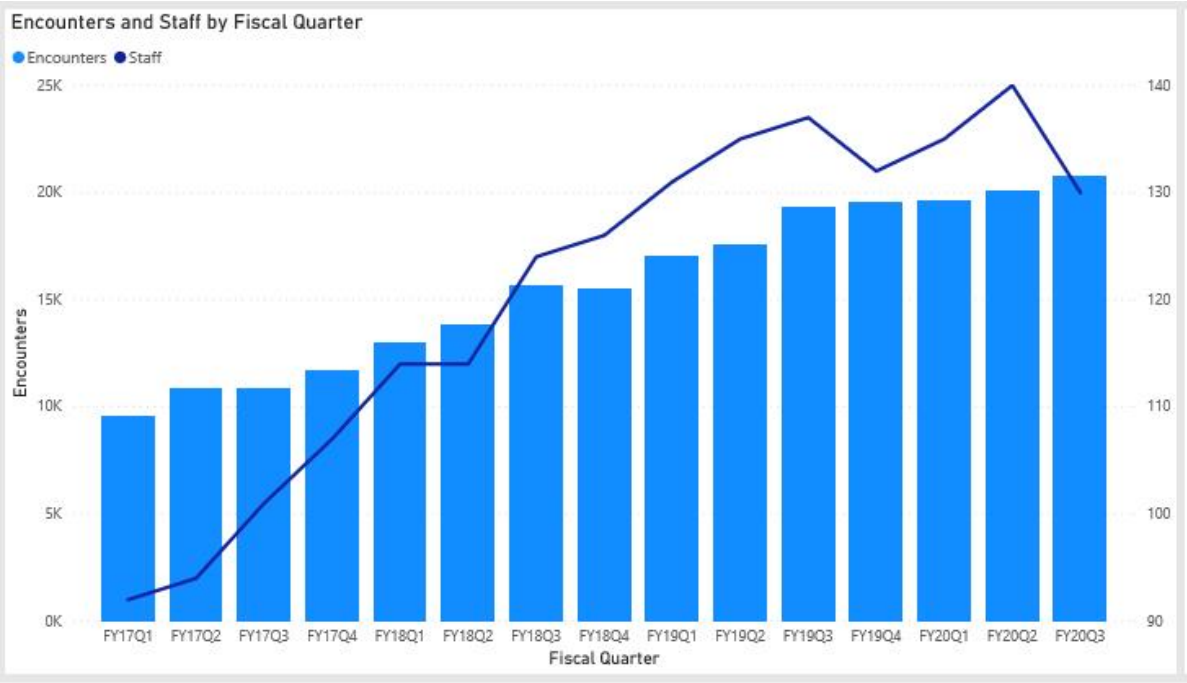


Figure 4: Oncology/Hematology practice area trends for all VA through FY20Q3



In the future, the PBM CPPO Oncology SME workgroup describe several elements as keys to successful integration of the CPP into the oncology practice and strong practices.

CONCLUSIONS

There is evidence that CPP improves access, chemotherapy safety and cost effectiveness when properly utilized. A recent systematic review of the literature found the value of the CPP in 4 key areas including clinical care, patient education, informatics and cost savings.[5] Additionally, multiple publications have demonstrated improvements in oral chemotherapy adherence, safety and even clinical outcomes with CPP involvement and/or CPP run oral chemotherapy clinics.[7,9-13] Given the anticipated shortage of oncology providers in the coming years, the CPP is a highly qualified provider that may be instrumental in addressing the workforce shortage and increasing access for the Veteran population. Given the needs of the facility, the CPP may be involved with oral chemotherapy management, outpatient and inpatient infusion chemotherapy management, sterile compounding of anticancer therapies, formulary management, drug information and informatics as well as investigational drug services. In FY20, there were 67,578 Oncology/Hematology patient care encounters with over 141,000 interventions made by CPP. The trends show that the number of encounters is continuing to escalate allowing improved access to care for Veterans with cancer. Additionally, the specialized training and knowledge of the CPP in complex anticancer therapy regimens as well as knowledge in safe ordering and handling makes their involvement essential in these areas to maintain safety. The CPP is an essential member of the Oncology/Hematology team with the ability to improve safety, expand access, and improve cost effectiveness when utilized appropriately.

REFERENCES

1. Association of American Medical Colleges Center for Workforce Studies: Forecasting the Supply of and Demand for Oncologists: A Report to the American Society of Clinical Oncology (ASCO) From the AAMC Center for Workforce Studies. March 2007. Accessed December 20, 2019.
2. Ignoffo R, Knapp K, Barnett M, Barbour SY, D'Amato S, et al. Board-Certified Oncology Pharmacists: Their Potential Contribution to Reducing a Shortfall in Oncology Patient Visits. *J Oncol Pract.* 2016; 12:4, e359-368.
3. Sessions JK, Valgus J, Barbour SY, Iacovelli L. Role of Oncology Clinical Pharmacists in Light of the Oncology Workforce Study. *J Oncol Pract*. 2010; 6:5, 270-272.
4. Vulaj V, Hough S, Bedard L, Farris K, Mackler E. Oncology Pharmacist Opportunities: Closing the Gap in Quality Care. *J Oncol Pract.* 2018; 14:6,e403-e411.
5. Segal EM, Bates J, Fleszar SL, Holle LM, Kennerly-Shah J, Rockey M, Jeffers K. Demonstrating the value of the oncology pharmacist within the healthcare team. J Oncol Pharm Practice. 2019; 25:8, 1945-1967.
6. Hematology/Oncology Pharmacy Association. Further Defining the Scope of Hematology/Oncology Pharmacy Practice. 2019. Available at: http://www.hoparx.org/images/hopa/resource-library/guidelines-standards/HOPA18_Scope-2_Web2.pdf. Accessed December 20, 2019.
7. Muluneh B, Schneider M, Faso A, Amerine L, Daniels R, Crisp B, Valgus J, Savage S. Improved Adherence Rates and Clinical Outcomes of an Integrated, Closed-Loop, Pharmacist-Led Oral Chemotherapy Management Program. *J Oncol Pract*. 2018; 14:6, e324-e334.
8. Gatwood J, Gatwood K, Gabre E, Alexander M. Impact of clinical pharmacists in outpatient oncology practices: A review. *Am J Health Syst Pharm*. 2017; 71:19, 1549-1557.
9. Battis B, Clifford L, Huq M, Pejoro E, Mamabourg S. The impacts of a pharmacist-managed outpatient clinic and chemotherapy directed electronic order sets for monitoring oral chemotherapy. *J Oncol Pham Pract*. 2017; 23, 582-590.

10. Finn A, Bondarenka C, Edwards K, Harwell R, Letton C, Perez A. Evaluation of electronic health record implementation on pharmacist interventions related to oral chemotherapy management. *J Oncol Pharm Pract.* 2017; 23, 563-574.
11. McNamara E, Redoutey L, Mackler E, Severson J, petersen L, Mahmood T. Improving oral oncolytic patient self-management. *J Oncol Pract.* 2016; 12, e864-e869.
12. Patel J, Holle L, Clement J, Bunz T, Niemann C, Chamberlin K. Impact of a pharamcist-led oral chemotherapy monitoring program in patients with metastatic castrate resistant prostate cancer. *J Oncol Pharm Pract.* 2016; 22, 777-783.
13. Shah N, Casella E, Capozzi D, Mcgettigan S, Gangadhar T, Schuchter L, Myers J. Improving the safety of oral chemotherapy at an academic medical center. *J Oncol Pract.* 2016; 12, e71-e76.