Quick Update on Pharmacy Standards and Medical Practices

Dawn Holcombe, MBA, FACMPE, ACHE
DGH Consulting

USP <797> - Sterile Compounding

- Current – existing <797> standards state that the standards apply to all entities, including medical practices
- Proposed <797>, published Aug 30, 2021 for comment, offers pathway to saying that medical practices are not compounding:

1.2 Administration

- For the purposes of this chapter, "administration" means the direct application of a sterile medicationto a single patient by injecting, infusing, or otherwise providing a sterile medication in its final form.
- Administration of medication is out of the scope of this chapter. Standard precautions such as theCenters for Disease Control and Prevention (CDC) safe injection practices apply to administration.

1.4 Preparation Per Approved Labeling

- Compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer andother manufacturer directions consistent with that labeling.
- Preparing a conventionally manufactured sterile product in accordance with the directions in themanufacturer's approved labeling is out of scope of this chapter only if:

1. The product is prepared as a single dose for an individual patient; and
2. The approved labeling includes information for the diluent, the resultant strength, the containerclosure system, and storage time.

Will I be held accountable for <797> Sterile Compounding standards?

- **Yes** – the current official <797> version states unequivocally that the standards apply to medical offices.
- **No** – (maybe) – the Proposed <797>, as currently worded, offers a pathway to exclude medical offices from sterile compounding standards IF they can show that all drugs are mixed as single doses for individual patients AND the package insert for all drugs includes the 4 required elements.
  - However – individual state regulations and legislation, depending upon how they are worded, may be still aligned with the current <797> wording, and therefore states could maintain that <797> applies. **In Georgia, current <797> and <800> wording applies due to state regulations dissonance**
- **Probably** – The <797> USP standards published by USP have no official weight for enforcement – they are guidelines. State regulations and legislation, and the intent and tenor of the state pharmacy leadership may or may not be in accord with the proposed <797> medical office pathway to not be considered to be sterile compounding.

USP <800> Hazardous Drugs

- Official as of Dec. 1, 2019
- Non compendial until current <797> is replaced with proposed <797>
- Georgia regulations make it law, as of Dec. 1. 2019
- Hazardous Drugs
  - Handling
  - Unpacking
  - Storage
  - Mixing
  - Disposal

Am I subject to <800> USP standards for hazardous drugs?

- **Yes** – The language of the <800> chapter clearly states that medical practices handling defined hazardous drugs are subject to the standards.
- **No** – Currently USP <800> is official but not compendial. This means that it is there as a guide, but not yet an actionable standard.
- **Maybe** – Some states (**GA included**) have their own language related to <800> in their existing regulations or legislation. Some have decided that there is insufficient evidence to adopt <800> in their regulations. <800> addresses handling, storage, disposal, as well as mixing and compounding. There is an argument to be made that medical practices, if determined under <797> to be not compounding, might claim an exemption from the sterile compounding requirements for hazardous drugs, but that has yet to be tested. Also unknown is whether individual states or other entities might choose to apply <800> standards in general to handling hazardous drugs for the non-mixing standards of <800>.

What is happening across the country?

- The National Association of Boards of Pharmacy – "National Reports Raise Questions about Oversight of Drug Compounding in Physician Offices", Innoventions Newsletter, March 2017, https://nabp.pharmacy/wp-content/uploads/2016/07/Innovations_March__2017_Final.pdf
- State of Ohio Board of Pharmacy – "Inspection Guide Terminal Distributor of Dangerous Drugs Clinic and Prescriber Office – Updated 3/30/2021 Effective 4/1/2021. https://pharmacy.ohio.gov/Documents/Licensing/TDDD/InspectionGuides/Clinic%20and%20Prescriber%20Office%20-%20Inspection%20Guide.pdf
- States of New Hampshire, Washington, Oklahoma, Connecticut – pharmacy inspectors enter medical practices without warning for inspections (2018 – 2022)
- 5 inspectors present on 6/7/2022. Administrator sequesters them in office, states no inspections happening today, let's talk. Hour of probing questions from inspectors, **knew they had no jurisdiction**. "If we feel patients are in danger or being harmed, will report practice to the FDA"

Georgia Definition of Compounding

- (6) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or de vice as the result of a practitioner's prescription drug order or initiative based on the relationship between the practitioner, patient, and pharmacist in the course of professional practice or for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine and regularly observed prescribing patterns. **Compounding does not include mixing, reconstituting, or similar acts that are performed in accordance with the directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.**
- (26)"Practitioner" or "practitioner of the healing arts" means a physician, dentist, podiatrist, or veterinarian and shall include any other person licensed under the laws of this state to use, mix, prepare, dispense, prescribe, and administer drugs in connection with medical treatment to the extent provided by the laws of this state.

- https://rules.sos.ga.gov/gac/480-11, Rules and Regulations State of Georgia, Rule 480-11-01 Definitions, Pharmaceutical Compounding

Georgia Statutes open a window for MDs

- Rule 480-11-.02 Compounded Drug Preparations (13) Practitioners who may lawfully compound pharmaceuticals for administering or dispensing to their own patients pursuant to O.C.G.A. Section 26-4-130 shall comply with all the provisions of this rule and other applicable Board laws, rules and regulations. https://rules.sos.ga.gov/gac/480-11

Georgia Pharmacy Board on <797> and <800>

- How does USP's announcement affect Georgia-permitted pharmacists and pharmacies?
- 1. **Existing USP chapters <795> and <797> will continue to be enforced**. Board inspections and investigative staff will continue to use the inspection forms and tools mapped to existing USP chapter requirements. As pharmacists know, under both federal law (the Drug Quality and Security Act) and Board rule (21 NCAC 46.2801), compounding activities must conform with the standards in these chapters. The revised chapters will be enforced when they go into effect. USP did not set a new effective date in its announcement today. https://gbp.georgia.gov/press-releases/2019-10-02/important-information-concerning-united-states-pharmacopeias-announcement)
- 2. Since USP has announced that as of December 1, 2019, chapter <800> is to be simply informational and not [compendially] applicable, GDNA will not be inspecting for compliance with chapter <800>, until such time that the revised versions of chapters <795> and <797> are made effective by USP
- Again, USP did not set a new effective date in its announcement. P**harmacies working toward chapter <800> compliance are strongly encouraged to take the time afforded by this delay to finalize those preparations**.
- http://ncbop.org/faqs/Pharmacist/faq_NEWUSP800.htm

GA law trumps USP “compendial”

- GA - Official Code of Georgia Annotated O.C.G.A. § 26-4-86
- TITLE 26 Food, Drugs, and Cosmetics > CHAPTER 4 Pharmacists and Pharmacies > Article 5 Prescription Drugs
- (a) The board shall establish rules and regulations governing the compounding and distribution of drug products by pharmacists, **practitioners**, and pharmacies licensed or registered by this state. **Such rules and regulations shall include provisions ensuring compliance with USP-NF standards.** (b) (1) All drug products compounded and labeled in accordance with board rules regarding pharmaceutical compounding shall be deemed to meet the labeling requirements of Chapter 13 of Title 16 and Chapters 3 and 4 of this title. (2)

Door open to interpretation

- GA - Official Code of Georgia Annotated O.C.G.A. § 26-4-40
- TITLE 26 Food, Drugs, and Cosmetics > CHAPTER 4 Pharmacists and Pharmacies > Article 3 Practice of Pharmacy
- (a) Except as otherwise provided in this chapter, it shall be unlawful for any individual to engage in the practice of pharmacy unless currently licensed to practice under the provisions of this chapter. (b) **Practitioners authorized under the laws of this state to compound drugs and to dispense drugs to their patients in the practice of their respective professions shall not be required to be licensed under the provisions of this chapter; however**, practitioners shall meet **the** same standards, record-keeping requirements, and all other requirements for the dispensing of drugs applicable to pharmacists.

Official VS Compendial = Official in GA

- Georgia Pharmacy Association Buzz – Andrew Kantor, 9/25/2016
- **Compounders, take note:**
- *USP <795>, <797>, and <825> are being postponed, but USP <800> WILL take effect in Georgia December 1.*
- The United States Pharmacopeia — USP — is postponing the implementation of the compounding standards in its chapters 795, 797, and 825, which were to be effective on December 1. No new effective date has been set.
- **General Chapter <800>, however, *will* become official on December 1, 2019.**
- Although USP says that 800 "is informational" only, Georgia law requires that pharmacists comply with USP-NF standards — so *USP <800> will be required by Georgia law as of December 1, 2019*.
- GPhA will of course keep you informed of any changes to these standards.

GASCO strategy re <797> and <800>

- **The GA BOP can elect at any time (especially if spurred on by NABP) to inspect for current <797> compliance. They may, or may not**.
- Competitors (hospital systems, specialty pharmacies, PBMS) may use compliance as a weapon against medical practices.

- **Suggested strategies:**
  - **Acquire pharmacy compliance software (I recommend Pestle (https://rxpestle.com/) I can set up a general demo for GASCO members if desired.**
  - **Review your own practices against the NOSN compliance preparedness review prepared for OHIO practices – I can provide this**
  - **We can do better.**
    - **SOPs, adverse event logs, designated responsible person, training, no open doors, separated cleaning, no particle exposure, aseptic technique SOP, diligence and awareness**

- **Where is the Science outreach to USP Board of Trustees – Resources and talking points available from NOSN, dawnho@aol.com**
  - **Professional standards chapters not supported with traditional USP scientific rigor**
  - **Allowing those opinion based chapters to stand opens them to be used as a weapon against safe delivery systems with different approaches**

What To Do If Inspectors Present at the Door?

- November 2016 for Oncology Practice Management USP <797> What to do When the FDA Comes Knocking on the Door of Your Cancer Center. https://oncpracticemanagement.com/issues/2016/november-2016-vol-6-no-11/843-usp-797-what-to-do-when-the-fda-comes-knocking-on-the-door-of-your-cancer-center
- Train your staff how to react and process to follow
- Sequester – do not take inside practice proper
- Call for help – risk management, legal, USP guidance
- Prepare talking points, and any documentation willing to share
- Know state regulations and how practice fits (or doesn't)
- Respond knowledgeably about USP chapters and lack of scientific justification compared to impact on patient access to care
- Escort them out politely within an hour.
- Prepare for followup

Employers – A growing disrupter for healthcare – more than health plans

Dawn Holcombe, MBA, FACMPE, ACHE
DGH Consulting

Employers are an Emerging Key Customer for Oncology Groups/Systems: What do you need to know and do to engage in productive conversations?"

- The role of employers is rapidly changing related to health care choices and the delivery system. In groups and individually, employers are an emerging key customer for any practice or health system. Today's discussion will help attendees:
  - Understand the changing role of employers as health care decisionmakers, and their perspectives and processes
  - Learn how to prepare for productive conversations with local employers
  - Assess your practice/health system from an employer's point of view
  - Identify opportunities for practice positioning with employers
  - Take away ideas to approach and engage employers

Understanding the employer market

Self Insured Employers are a large market

- 78.5% of employers with 500 or more employees offered a self-insured health plan (more than 56,000 plans covering more than 75 million lives
- Their strategies for business goals for benefits include:
  - Medical cost reduction through plan design
  - Medical cost reduction through marketplace innovation
  - Improved member engagement in health and wellness
  - Improved workplace engagement and performance

- Might consider leading edge **solutions if the return on investment is worth the risk and hassle**
  - Can you do what you say you will do and do it well?
  - Do you have a proven track record?
  - What will the service experience b fore the employees? For their families?
  - What will we see from you?
  - What kind of reporting do you offer back to us?
  - What is our return on investment?
  - Are you willing to share any risk?
  - Claims of medical cost reduction need to be credible and data driven.

- Ronald Leopold, "How Healthtech Companies Can Successful Access the Self-Insured Employer Market", Mdisrupt, 11/7/2019, last accessed 12/7/2021 at https://mdisrupt.com/blog/healthtech/strategies-self-insured-employer-market/#:~:text=The%20self-insured%20employer%20%28SIE%29%20marketplace%20is%20enormous.%20And,or%20more%20employees%20offered%20a%20self-insured%20health%20plan.

Self-funded employers are gathering for better healthcare options

- National alliance of Healthcare Purchaser Coalitions 46 Members https://www.nationalalliancehealth.org/home
- 2019 Report "Achieving Value in Cancer Care" https://higherlogicdownload.s3.amazonaws.com/NAHPC/3d988744-80e1-414b-8881-aa2c98621788/UploadedImages/Achieving_Value_in_Cancer_Care_FINAL_01_2019.pdf
- North Carolina Business Group on Health https://ncbgh.org
  - "N.C. Business Group on Health on a mission to lower healthcare costs", Triad Business Journal, 12/24/2020, last accessed on 12/7/2021 at https://www.bizjournals.com/triad/news/2020/12/24/ncbgh-biosimilars-healthcare.html

Employer Benefits Guidance

- NCCN® launched June 2, 2021 NCCN Employer Toolkit - a free online resource that contains information such as basic medical definitions as well as suggestions on how to help employees estimate and plan for out-of-pocket costs. https://www.nccn.org/business-policy/business/employer-resources/employer-toolkit
- 2021 CancerCare introduced Employee Protection Toolkit: Best Practices for Prescription Drug Benefit Design - https://media.cancercare.org/publications/original/447-CancerCare-EmployeeProtection-Toolkit-digital.pdf
- COA, CancerCare started TimeToScreen in Nov. 2021, driving cancer screenings at employers. https://timetoscreen.org/employer-toolkit/

What employers are saying about cancer care

- "What Purchasers need to know about Cancer" https://higherlogicdownload.s3.amazonaws.com/NAHPC/3d988744-80e1-414b-8881-aa2c98621788/UploadedFiles/T5nwtvKTbmCeljXjojJs_National%20Alliance%20Purchasers%20Know%20About%20Cancer%20Care%20_infographic_3_08_2019.pdf
- "Delivering Value in Cancer Care: The Employer Perspective" The Northeast Business Group on Health, November 2019.
  - In March 2019, NEBGH brought stakeholders together for a Value in Cancer Care roundtable. **This guide,** *Delivering Value in Cancer Care: The Employer Perspective*, **includes actions, resources and information gleaned from that discussion, from interviews with national employers, health plans and care providers, and a survey of 75 employers across the U.S.**
- **In development –** Association of Corporate Health Risk Managers (ACHRM) fielding, assessing and creating best of class recommendations for member employers for cancer related resources, programs and apps.

To Learn how they think….read what they write

National Alliance of Healthcare Purchaser Coalitions
Driving Innovation, Health and Value

ACHIEVING VALUE IN CANCER CARE

Striving for Patient-centered Care

A Deep Dive Powered by eValue8

DECEMBER 2018

EMPLOYER CHECKLIST

APPENDIX I

(summarizes all objectives and recommendations outlined in this report)

The following provides potential key objectives to improve the value and outcomes of your organization's cancer care benefits as well as suggested areas and actions that should be addressed with your health plan(s).

Navigation, Advocacy & Support

OBJECTIVES:

a. Develop and communicate a patient-centered approach for cancer care benefits that provides comprehensive support to employees and families impacted

b. Obtain health plan commitment to patient-centered cancer care and match patients with the appropriate cancer care support option available (through plan, provider/cancer center or third-party-sponsored)

c. Set expectations for delineation of responsibility for provision of cancer support (not clinical) services

d. Review current coverage and policies that impact cancer care

e. Determine strategies that mitigate the related financial concerns associated with cancer patients

f. Review End-of-life Programs to determine appropriate benchmarks and care strategies are in place

CURRENT NAVIGATION SERVICES

- Insist your health plan review cancer care program offerings and assess the extent to which they provide frequently needed services specific to cancer patients both within and outside the PCMH/COEs. Also be sure to review all services provided for better care coordination and reduce duplication, as appropriate.

SELECTED COVERAGE POLICIES

- Review current coverage policies to assess against coverage needs including the following and update as necessary
  - Appropriate genetic testing is in place that guides effective treatment for specific cancers
  - Nutritional support protocols are in place to maintain optimal weight for oncology treatments
  - Effectiveness of various pain management/complementary therapies and appropriate coverage options

MEMBERS' FINANCIAL CONCERNS

- Monitor for non-adherence to cancer therapy drugs and request a report that identifies reasons for non-adherence
- Confirm health plan and PBM provide timely notifications to members on the overall cost of therapy treatments when the request for high-cost medications is received
- For in-network COE/hospital/facility, insist that strategies are in place to mitigate catastrophic costs for instances where member receives appropriate cancer treating agents (oral and/or injectable) that are not on preferred drug list (PDL) while undergoing treatment
- Confirm availability of financial counseling services through health plan and/or EAP and that consistent member communications of these services are in place

END-OF-LIFE PROGRAMS

- Request data on participation in end-of-life programs, including applicable Core Quality Measures (see: Provider Performance Measurement)
- Determine how the health plan collects, or plans to collect, data on events near the end of life (percentage and length of participation, ER visits, late admission to hospice, chemotherapy, ICU admission) necessary to report Core Quality Measures, including assessment of the feasibility of collecting mortality data from eligibility disenrollment and/or other sources

Clinical Support

OBJECTIVES:

a. Encourage pre-diagnosis and diagnosis screening policies, metrics, appropriate use of cancer treatments, new expensive drugs, personalized medicine and use of incentives
b. Enable Prior Authorization (PA) program design that minimizes stress for patients, facilitates timely and appropriate treatment and allows for immediate, automated approval for standard therapy
c. Support payment transformation that rewards better value and patient-centered outcomes
d. Implement broad program support for patients and families – clinical, nutritional, psychological, financial, end of life, etc.
e. Ensure quality & performance improvement with quarterly reporting of key performance metrics and progress against specific plans to improve related program and payment strategies

PRE-DIAGNOSIS AND DIAGNOSIS

- Confirm use of HEDIS cancer screening rates in your markets especially in PCMH/ ACO populations
- Determine how health plan provides "active" support to clinicians for use of appropriate tests such as use of incentives, contractual/employment requirement and feedback reporting

TREATMENT

- Review criteria for the Plan's or PBM's prior authorization process for drugs, radiation therapy and other cancer therapies, including process for updating criteria
- Determine activity metrics for prior authorization process that includes approvals, denials, and turnaround time, including detailed definitions of program metrics
- Review how health plans/PBMs work with clinicians to expedite receipt of needed clinical information for PA decisions, including processes to identify drugs requiring frequent PAs and/or high percentage of approvals by prescriber
- Determine if PCMH, COE, ACO programs exempt providers from PA. If so, assess why and if it is appropriate.
- Confirm use of (or plans to use) Pharmacy Quality Alliance (PQA) specifications on monitoring primary non-fulfillment

ENSURING QUALITY AND PERFORMANCE

- Determine the criteria and evaluation outcomes measures needed beyond credentialing and Board certification used for selecting current oncology networks, COEs and radiation facilities/providers, that will promote higher quality and performance
- Request patient safety data e.g., chemotherapy and/or radiation overdose and use to determine any changes to policies or other processes associated with patient care
- Determine availability of cancer PCMHs, including details of plan standards, required services and plan-provided resources (refer to "Navigation and Care Delivery Platforms" and "Cancer Patient-Centered Medical Home (PCMH)/Cancer Medical Team)")
- Implement quantifiable, quality measures (e.g., proportion admitted to hospice by oncology providers for more than 3 days) especially those in PCMH and COEs. Include timeline/plan of action for implementation feedback reporting and inclusion in payment models

PAYMENT INNOVATION

- Discuss payment innovation developments and efforts to push on moving away from FFS arrangements

Shared Decision Making/Treatment Option Support

OBJECTIVES:

a. Move patient decisions from "informed consent" to "informed decision" through treatment options, decision support and SDM tool(s)/resources

b. Ensure reporting with actionable analyses for decision making, including quarterly reports for high priority areas (e.g., prior authorization processes, End-of-life programs)

c. Monitor and improve optimization of site of care

d. Shift toward outcomes-based contracting over time

e. Periodically assess updates to programs and support services

INFORMED PATIENT DECISION-MAKING

- Review health plan's shared decision making(SDM)/treatment option support tool for proper content, functionality, member profile and cost estimate features
- Determine current utilization of SDM by cancer patients, by type of cancer and with and without Certified Patient Decision Aids (PDAs) and if not optimal, determine plan of action to enhance for better usage/engagement
- Request samples of quality information displayed in directories and available to members
- Determine if optimal genetic risk evaluation/screening strategy(ies) are in place to ensure appropriate counseling and decision-making

ACTIONABLE REPORTS

- Request that reports be current and automated and provide custom actionable reporting options
- Request reports by "offering" (Cancer PCMH, COE, Specialized Case Management) that includes:
  - %of patients participating and length of participation
  - Number of interactions with cancer patients
  - %of cancer patients identified by tactic (e.g., PA, pharmacy, referral, claims, etc.)
  - Overlap of patients
  - Detailed definitions of reported metrics

SITE OF CARE OPTIMIZATION

- Request that evidence is used to determine best value sites of care, tactics for steering patients to highest value sites of care and that steerage results by tactic are monitored or tracked

OUTCOMES BASED CONTRACTING

- Review oncology products and services that could be included in outcomes-based contracts (including products of specific interest to employer)

National Alliance of Healthcare Purchaser Coalitions
Driving Innovation, Health and Value

WHAT PURCHASERS NEED TO KNOW ABOUT CANCER

Based on National Alliance of Healthcare Purchaser Coalitions' eValue8 Deep Dive

ARE YOUR HEALTH PLANS KEEPING PACE WITH THE RAPID ADVANCES IN CANCER CARE?

Cancer mortality rates are dropping

25%

Drop in cancer mortality rate since early 2000s[1]

Costs of treatment are skyrocketing

$ 100,000-400,000

Cost per year for many new cancer drugs

Inconsistent coding and care pathways are a roadblock to managing cost and quality

700,000

Genetic biomarker tests

BUT ONLY

200

Lab billing codes

% of Rx claims subject to prior authorization

<5% to >75%

[1]Unless otherwise indicated, references may be found in the National Alliance's publication, *Achieving Value in Cancer Care*

Some types of cancer can now be managed like a chronic condition

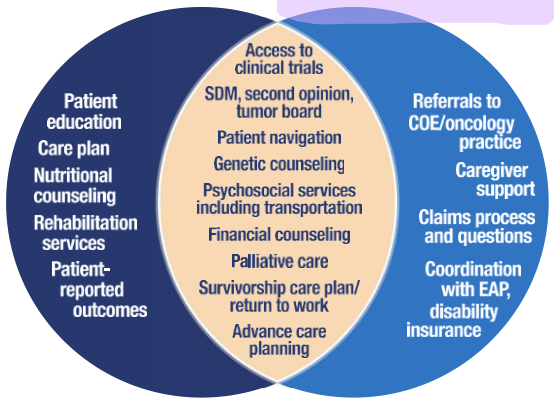
ARE YOUR EMPLOYEES GETTING THE RIGHT CARE?

Milliman reported that the cost of chemotherapy can vary by 30% to 50% between a physician's office and a hospital outpatient setting

National plans typically adapt existing approaches to encourage appropriate care

- Most rely on prior authorization and case management
- Most offer web-based tools
- Few use feedback reporting
- None use incentive payments

CANCER CARE IS EVOLVING TO DELIVER PATIENT-CENTERED CARE

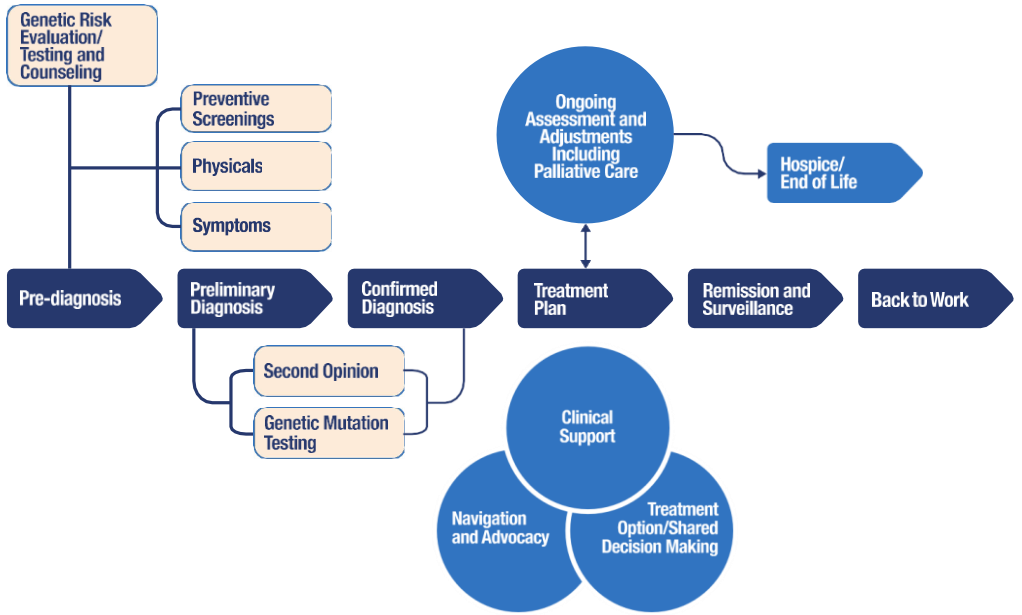


The majority of patient-centered care is offered by three entities:

1. Providers, e.g., Cancer Patient-Centered Medical Home (PCMH),
2. Health plans (e.g., Specialized Cancer Case Management), or
3. Employers and third-party contractors

Care is often not coordinated among these three. "Cancer Huddles" are one way to bring them together to ensure superior patient and family support.

PATIENT-CENTERED CANCER JOURNEY



Need for patient and caregiver psychosocial support, coordination and accommodation across the journey

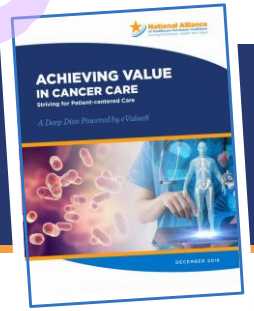
WHAT PURCHASERS CAN DO ABOUT CANCER*

- ☐ Provide benefits, navigation, advocacy and support to ensure a Patient-Centered Cancer Journey
- ☐ Work with health plans, providers and pharmacy benefit managers to root out waste related to inappropriate or low-value care
- ☐ Have your health plan measure inappropriate care and care inconsistent with best practice guidelines (e.g., frequency of colonoscopies, breast cancer screenings, Pap tests)

Only 1 in 5 plans collects 14 health-industry-developed core quality measures.
For example:

- Proportion with more than one emergency room visit in the last 30 days of life
- Proportion admitted to the ICU in the last 30 days of life
- Proportion not admitted to hospice
- Proportion admitted to hospice for less than 3 days

CONNECT WITH US: nationalalliancehealth.org
twitter.com/ntlalliancehlth
linkedin.com/company/national-alliance/



For more information, see our detailed report, which includes a comprehensive employer checklist

**For a comprehensive employer checklist, see the full report, "Achieving Value in Cancer Care."*

National Alliance of Healthcare Purchaser Coalitions
Driving Innovation, Health and Value

CEO Roundtable on Cancer

- https://www.ceoroundtableoncancer.org/about
- Today, the *CEO Roundtable on Cancer*, chartered as a 501(c)(3) nonprofit organization in 2005, works to develop and implement initiatives that reduce the risk of cancer, enable early diagnosis, facilitate access to the best available treatments, and hasten the discovery of novel and more effective anti-cancer therapies to help eliminate cancer as a personal disease and public health problem.
- ***CEO Cancer Gold Standard™*** **–** An employer-led, wellness accreditation program (over 200 have earned accreditation) addressing:
  - Health Education & Navigation
  - Prevention & Early Detection
  - Advancing Treatment
  - Survivorship
  - Well-Being
- 1204 Village Market Place
  Suite 288
  Morrisville, NC 27560

https://online.flippingbook.com/view/654153/12/

Delivering Value in Cancer Care: The Employer Perspective

November 2019

NORTHEAST BUSINESS GROUP ON HEALTH

solutionscenter

Designing Your Cancer Care Benefits to Deliver Value

In this section, you'll find details on key services to consider when designing your benefits to support high-value cancer care.

Cancer Prevention and Wellness Programs

An estimated 40% of cancers in the U.S. — and nearly half of all deaths from cancer — are caused by potentially avoidable risk factors. These include tobacco use, poor diet, alcohol use, physical inactivity and obesity.[13] Skin cancer may be prevented with sun protection, and widespread human papillomavirus (HPV) vaccination use may prevent 90% of cervical cancers.[14]

Some employers design holistic and engaging wellness programs for employees that address cancer risks. These include:

- Tobacco-free policies that support employees who wish to quit
- Access to healthy foods and nutrition education at work
- Education on alcohol risks
- Education on preventing harmful exposure to UV light and skin screenings
- Onsite fitness centers, walking trails, and accessible and welcoming stairwells
- Full coverage for recommended cancer screenings
- Full coverage for HPV vaccine for all teenage dependents

13 https://onlinelibrary.wiley.com/doi/full/10.3322/caac.21440

14 https://www.cancer.gov/about-cancer/causes-prevention/risk/infectious-agents/hpv-vaccine-fact-sheet

CBS Corporation: Screening Programs

To improve cancer screening rates among employees, CBS, partnering with Memorial Sloan Kettering Cancer Center, hosted a number of screening programs for employees. MSK physicians came to CBS to deliver targeted education and offer screenings for lung, breast and colon cancer. CBS Vice President of Employee Engagement Michelle Martin saw this not only as a great educational opportunity but also as a chance to remove some fear and emphasize the importance of screening and early detection. The effort increased screening rates among CBS employees, and the company hopes to offer similar programs in the future.

> **"Providing this service and education around the topic of cancer to our employees is critical. This program was a way for us to increase awareness about cancer screenings and have a credible source such as MSK behind us to help deliver the message."**
>
> Michelle Martin, Vice President of Employee Engagement, CBS Corporation

PepsiCo: Cancer Care Navigation and Value

PepsiCo developed an integrated health advocacy/navigation model that places its nearly 90,000 employees at the center of the value conversation. The program, Health ACE (Assist, Connect and Educate), provides a customer service-focused experience to help employees manage every aspect of their health, including specialized services for cancer patients and survivors. When a family faces a cancer diagnosis, an oncology health professional is assigned to help them understand the diagnosis, discuss treatment options, and determine other needed services (social work, mental healthcare, elder care, medication assistance, etc.). This helps ensure that employees have access to the right care at the right time.

PepsiCo views its Health ACE program as more than a navigation service. In fact, the program is an opportunity for the company, its vendors and health plans to unite in a common purpose — determining what employees value in cancer care. The program support team and key care stakeholders meet monthly to align objectives.

> **"You can develop all the programs you want, but if you don't integrate them behind the scenes and stay actively involved through the process, you won't make much progress. The Health ACE program provides an opportunity for the company, our vendors and our carriers to come together for one common purpose: our members. We want our members to know we are here with them and for them."**
>
> Deb Mackin, Program Benefits Manager, PepsiCo

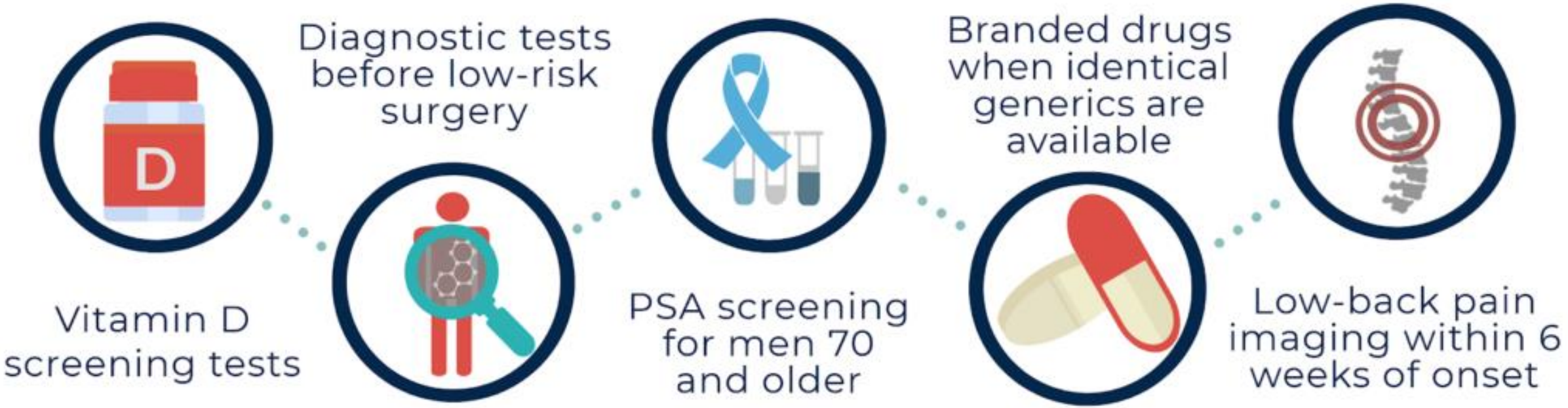
Checklist: Where Do You Stand?

The following questions will help you determine where you might make changes to enhance the value of the cancer benefits you provide:

- ☐ What services are currently available to your employees?
- ☐ Do you provide education on and access to appropriate cancer screenings? Is uptake over 80%?
- ☐ Do your employees receive help in the form of second opinions and care navigation?
- ☐ Do you help direct employees to preferred sites-of-care either through your health plan's network or a CoE program?
- ☐ Do you communicate regularly with employees about benefit offerings? How are employees with a new cancer diagnosis able to access the information they need?
- ☐ Do employees understand the benefits and services you offer? How do you measure their understanding?
- ☐ Do your health plans and vendors share data with you? How do you use this data to inform your decision making?
- ☐ Do you provide data to stakeholders such as hospitals, health plans and pharmaceutical companies? Do you advocate for data sharing?
- ☐ Do you check in regularly with vendors, and do your vendors talk with one another? Have you considered the Cancer Care Huddle model?
- ☐ Do you meet regularly with other employers to discuss challenges you're facing related to providing cancer care to your employees? Do you meet with other stakeholders?

University of Michigan Center for Value-Based Insurance Design "Top-Five" list of low-value clinical services for purchasers to target for reduction

Low-value care can be defined as "[s]ervices that provide little or no benefit to patients, have potential to cause harm, incur unnecessary cost to patients, or waste limited healthcare resources," and contributes to over $345 billion annually in wasteful health spending.



https://vbidcenter.org/initiatives/low-value-care/

So how to Get Started?

National Oncology State Network (NOSN) www.nosn.info

Collaborative Care Team

- Facilitating collaboration between providers and employers/managed care locally, with national strategic support

State leader opening to represent North Carolina

Resources to help move forward

- National Oncology State Network (NOSN) – collaboration to support equal cancer care access across state lines
  - Volunteers
  - 43 states
  - a nonprofit action organization established by state leaders collaborating on emerging state issues in order to strengthen cancer care and policy across the country
  - an incubator, a promoter of shared ideas and resources, and collaborator at the state level to advance the cause of oncology for national uniformity
  - “Strategic leadership in cancer care is built on both innovation and collaboration. NOSN unites emerging and individual state issues and concerns into national awareness and action.” Dawn Holcombe, NOSN President
  - Georgia is a NOSN member

NOSN Teams

- State Legislative
- Pharmacy
- Policy
- Collaborative Care - COLLABORATIVE CARE TEAM:

- Sheryl Riley (Chair), Patricia Alvarez-Sahagun (AZ), LuAnne Bankert, Peggy Barton, Christina Day (AbbVie), Dr. Dane Dickson, Nichole East, Jason Enlow (AbbVie), Matt Farber (AbbVie), Leslie Fox (J&J), Diane Gerards-Benage, **Loretta Goodson**, Katherine Grigsby, Dawn Holcombe, Ellen Ivey (J&J), Mariana Lamb, Rebecca Leuken (J&J), Damon Madison (AZ), Dr. Rene Rothstein-Rubin, Patricia Slade (J&J), and Kim Woofter.
- Purpose: : The Team is responsible for working with employer groups and business coalitions on access to oncology care for their employees.
- Goals: Educate employer groups and business coalitions about the high cost of cancer care and what issues are involved, such as outdated payment models, high site of service costs, and
- expensive middlemen in order to provide better access to cancer care for their employees
- Next Steps: Partners from California and Texas began their work in early 2021
- Accomplishments:
- Developed template that includes:
    - • How to identify the players and their roles within your individual states
    - • Understand the book of business and state dynamics
    - • How to start the conversation
    - • Pitfalls
- • Connecticut is already working on this and California and Texas will be joining soon

Step 1 – Research before making that first call

First – Research the landscape

To be completed by: SR

Deadline: 04/01/2020

Done?	Category	Type	Task	Due By	Notes
☐	**Who in your region should you target**	*Research*	review what is happening in your state, county or local markets		
☐			national business coalition on health in your area		
☐			regional business coalition on health in your area		
☐			state business coalition on health in your area		
			Talked to payers and see any interest in partnership ex. Your physicians speaking a employer events, educations, health fairs		
			large and midsize employer groups- look at current news about them on website to see what initiatives they are focused on		
			Ensure employer information is in your PMS, demographic investigations and any trends of specific employers referrals		
			Top employer reports monitored from your PMS, trends, what HPs are the employers selecting?		
		choose employer to speak with: criteria	Self funded		
			size- number of covered lives		
			age and make up of the population		

Key elements that drive the employers

Overall survival rate for your patient population by cancer type
hospitalization rates
medication discount programs
speak about closing the gap between access to and actual utilization
Do local community practices have access to clinical trials and other program academic centers have

Be prepared to answer these questions

do you have ancillary services- behavior health, social services , nutrition and PT as part of your program

What is your survival rate for different cancer conditions?

Do you have a return to work program
Can employees work while going through cancer treatment, if not what are the time frames for return to work
Screening, nutritional and social services - included
Benefits of community practices and local hospital vs academic centers

Step 2 – Engage, Listen, Support – Find Mutual Opportunities

Second - Start the Conversation

To be completed by: SR

Deadline: 04/01/2020

Done?	Category	Type	Task	Due By	Notes
	Mental prep		Employers do not want to pay for high quality cancer care, they assume you are already a quality provider		
			Know your number, how many patient of this group do you see, what have been the outcomes and cost		
			know your billed vs allowable		
			be prepared to hear that they do not like some of things your practice has done		
			Do not go in thinking you are going to sell them something		
			Do not go in to the meeting with an ego		
			HELP ME HELP YOU		
			do not suffer from foot in mouth disease , **listen more than you talk**		
			Must build trust and relationship over time = focus on win-win		
	How to start conversation				
			Establish trust with pricing transparency		
			offer a tour or open house of the cancer center or largest office		
			schedule small face to face meetings with key individuals, such as benefit managers, Human resources, employee representatives		
			find out if they have a yearly health fair and offer to be here to discuss prevention		
			offer prevention and screen seminars in your clinic or office		
			Discuss data analysis - come with a prepared template of needs (keep it simple)		
			important to note most self funded have a TPA (third party administrator) who manages and controls data and they do not like giving it up		
			Nothing like testimony from patients on the care they receive at your center, brochures, videos that you can share		
			good blind case studies		

Step 3 – Expand, Grow Together, Share information, Set New Targets and Strategies

Third – Collaboration

To be completed by: SR

Deadline: 04/01/2020

Done?	Category	Type	Task	Due By	Notes
	once relationship is established	*total cost of care*	total number of cancer patient		obtain data - give them a template of what you need, knowing you will never get all you ask for or in the format requested (complete data analysis)
			total number of cancer patient with co-morbidities- broke out by 1-3, 4 to 6 and greater than 6		
			total number of cancer patient by age		
			cancer type		
			stage		
			treatment type		
			cancer type by treatment type and cost		
			medication cost		
			ancillary services cost		
			In pt.		
			out pt.		
			radiation		
			screening and labs		
	Share findings with client	*total practice cost of care*	individual center -cost of car		then broken out by
			MD- cost by MD		
			Cancer - cost by cancer type -		
			site of care - site of care		
			ancillary services - cost of care		
			ED and re admits - type of S/E and cost total and per encounter		
	Interventions from data and lessons learned	*total cost*	prevention screening, testing		Build a presentation outlining areas of improvement for both physicians and self funded
			treatment IV, PO		
			side effect mgt prevention- input, output, ED, SNF, hospice and palliative care		
			SDOH community resources and services		
			survivorship nutrition, exercise, behavioral health		
		overall improved outcomes and cost savings	Develop metric demonstrating that you are measuring the practice and continual improvement		
			Patient wait time		
			Apt. wait time		
			Education provided to patients		
			Nurse Navigation		
			IP days or visits		
			ER visits		If possible, research baseline on cost of IP and ER visits and savings

Building Relationships, One Step at a time

Helium hand

- Data interpretation
- Strategy
- opportunities

If not you, than who?

If You/ve Seen One Relationship, Have seen One – flexibility. Read the Room.

We all care about the population of this area

Start easy – screenings, be a resource for review of the many apps and ideas

Unintended consequences

- 10% dose reduction
- Iron
- Whitebagging
- Alternative funding programs
- Targeting high risk cancer with multiple comorbidities
- Spsecialist involvement in primary care population management

Final Takeaways – Outreach to Employers

- Assess the market
- Understand their perspective (You also are an employer)
- Prepare, prepare, prepare
- Listen, Probe, Find Common Ground
- Show willingness to sit at the table
- Despite active discussion, opportunities abound for collaboration and pilots

Thank You, and Good Luck

Dawn Holcombe, MBA, FACMPE
DGH Consulting
33 Woodmar Circle
South Windsor, CT 06074

860-305-4510
dawnho@aol.com
www.dghconsulting.net