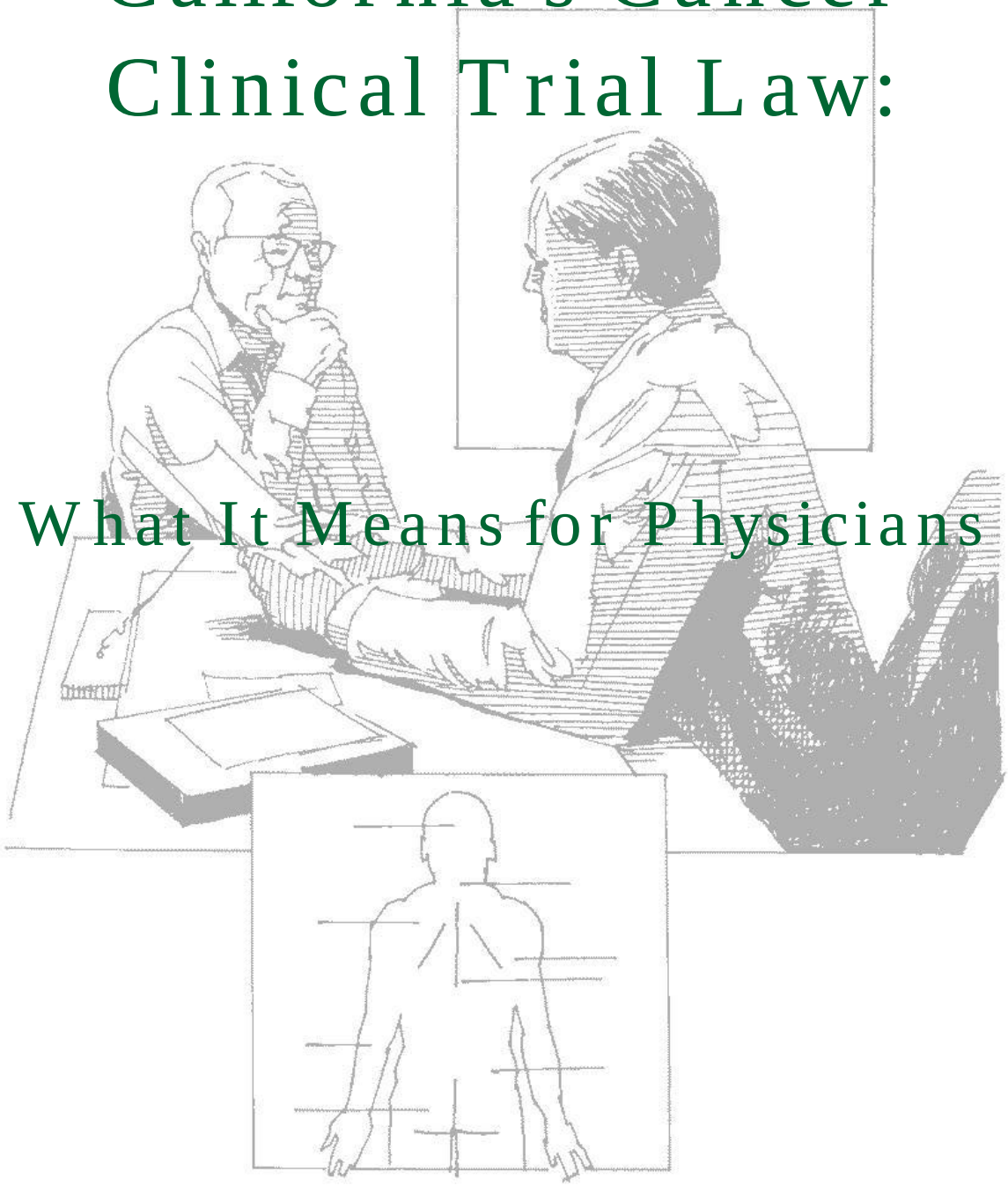
California's Cancer Clinical Trial Law:



What It Means for Physicians

The law offers patients a measure of financial security, because it gives them the freedom to enroll in selected clinical trials, with the assurance of coverage and reimbursement by their health plans.

Introduction

As an oncologist, you have a range of treatment options for your cancer patients. Patients initiating therapy, or who are refractory to established treatments, may benefit from the investigational drugs or protocols available to them in a clinical trial. This brochure, sponsored by the Association of Northern California Oncologists (ANCO) and the Medical Oncology Association of Southern California (MOASC) and researched and written by State Health Policy Solutions, explains California law regarding clinical trials, which can help ensure your patients' access to high quality studies.

The law offers patients a measure of financial security, because it gives them the freedom to enroll in selected clinical trials, with the assurance of coverage and reimbursement by their health plans. The law requires health maintenance organizations (HMOs), preferred provider organizations (PPOs), and point of service (POS) plans to cover and pay for the costs associated with routine patient care services in approved clinical trials.

In the sections below, you will learn about how the law may benefit your patients and affect you as an oncologist. You will also find answers to frequently asked questions about the statute. Finally, we have included telephone numbers that will give you access to additional information.

California's Clinical Trial Law:

Information for physicians and their practice managers…

The goal of the clinical trial law is to require health plans to pay for routine patient care costs when enrollees participate in certain federally-approved studies. The law (Section 1370.6 of the Health and Safety Code; Section 10145.4 of the Insurance Code; and Sections 14087.11, 14132.98, and 14132.99 of the Welfare and Institutions Code), took effect January 1, 2002.

If your patient has not responded to standard treatment, in some cases, you and he or she may conclude that enrolling in a clinical trial is feasible and desirable. Under the terms of the law, the clinical trial must either be designed to assess the efficacy of an investigational or experimental therapy, or it may compare two existing standard therapies or variations of the standard therapies. As long as the clinical trial has meaningful potential benefit (beyond just measuring toxicity), private health plans, HMOs, and Medi-Cal must cover and pay for the routine costs of treatment.

What should you tell your patients?

It is important for you to tell your patients who are enrolled in, or considering enrolling in, a clinical trial about the law because it affords them the financial freedom to participate in a study and benefit from innovative therapies and protocols, with far fewer worries about how to pay for the care. When they

The law specifically covers cancer patients who participate in a Phase I, II, III, or IV clinical trial for cancer treatment.

enroll in a qualified trial, their health plan will bear a portion of the cost of care in the study. Historically, health plans have not paid for these costs because they are typically excluded from most consumers' and employers' contracts as experimental or investigational care.

Health plan policies regarding coverage for care in clinical trials once varied widely. One important effect of the law is that it establishes a level playing field for all health plans in California, as well as Medi-Cal. It defines what type of trials are covered as well as what items health plans must pay for and what they are not required to cover or reimburse to you or your patient. Patients are still responsible for their share of the treatment; they must still pay the co-payments and deductibles that their contract or their employer's contract requires them to pay.

This is an important advance for the cause of clinical trial enrollment. Studies show that patients are reluctant to enroll in clinical trials because they do not understand the potential benefits and because they think they will have to pay more for the treatments. You can now inform your patients about the potential benefits of participation and help allay their fears about costs.

Who is covered?

The law specifically covers cancer patients who participate in a Phase I, II, III, or IV clinical trial for cancer treatment. In order for a health plan to cover the routine patient care costs of care in the study, one of the National Institutes of Health, the U.S. Food and Drug Administration, Department of Defense, or Department of Veterans Affairs must have approved the trial protocol. The statute does NOT cover protocols not approved by one of these entities.

Any investigational drugs that are exempt from federal regulations for new drug applications are also covered under this law. You should confirm that a clinical trial falls in one of these categories before enrolling a patient and seeking coverage and reimbursement from a health plan. You may wish to get prior approval from the patient's health plan to ensure coverage and reimbursement and minimize the possibility of payment problems later on.

What is covered?

The law defines routine health care services as health care services that would be provided whether or not the patient was enrolled in a trial. Health plans must cover and pay for drugs, devices, and services related to the clinical trial that they would cover even if the patient were not in a study. For example, doctor visits, hospital stays, and medical testing all fall in this category. Administering the investigational therapy, monitoring it, and preventing or diagnosing and treating complications are also covered.

If you have any doubts about whether a specific item is covered, contact your patient's health plan.

Health plans are not required to cover the cost of the experimental drug or device. These costs are typically borne by the pharmaceutical company, government agency, or other entity that is conducting the trial.

How much do health plans have to pay?

The law establishes a framework for how physicians and hospitals are paid for the services they provide to patients in qualified clinical trials. If you have a contract with a health plan (i.e., you are a participating provider), the health plan must pay you at rates agreed upon in your contract.

The law treats non-participating providers differently. If you are a non-participating provider, there are two potential payment levels. The health plan can pay you at a negotiated rate; or, it is allowed to reimburse routine patient care costs at the lowest rate that it would pay to a participating provider.

What is not covered?

Health plans are not required to cover or pay for:

- investigational drugs or devices that are not yet FDA-approved,
- non-health care services such as travel, housing, companion expenses,
- trial data collection or management costs, or
- any sponsor-supplied products and services.

These costs are typically borne by the pharmaceutical company, government agency, or other entity that is conducting the trial.

Health plans are not responsible to cover and pay for any services that are not covered by the patient's contract. For example, a patient who would normally have to pay out of pocket for in-home infusion of drugs will still have to do this, if home-infusion therapy is part of the clinical trial protocol. Finally, health plans may limit their coverage and reimbursement for care in a qualified clinical trial only to sites in California. They are required to cover and pay for care at sites outside the state only if a California provider does not offer the protocol.

What health plans are bound by the law and which ones are not?

The law applies to most health plans that are licensed in the state of California. It applies to HMOs, PPOs, POS plans, and all Blue Cross Blue Shield plans. It also applies to Medi-Cal, the state's health insurance program for low-income participants. Medicare participants are already covered for clinical trials. You can find additional information on Medicare coverage at www.Medicare.gov and you can download a brochure on Medicare coverage from (www.medicare.gov/publications/pubs/pdf/clinical.pdf).

The law does not apply to vision-only, dental-only, accident-only, specified disease, or hospital indemnity, Medicare supplemental , CHAMPUS supplemental plans, long-term care, or disability

The law applies to most health plans that are licensed in the state of California. It applies to all HMOs, PPOs, POS plans, and all Blue Cross Blue Shield plans. It also applies to Medi-Cal...

income insurance plans. The law also may not apply to plans that are self-insured by the patient's employer or plans that are covered by the federal ERISA law. If you have a patient whose coverage is excluded by one of these last two circumstances, you and your patient will have to negotiate coverage with the health plan or employer because they are not required by law to cover care in clinical trials. One-third to one-half of all privately insured patients in California are not covered by the law, so it is important to determine coverage before enrolling a patient in a study.

Potential problems and implications for you

The clinical trial law states that the protocol must have "meaningful potential benefit to the enrollee" and that the endpoint of the trial "shall not be defined exclusively to test toxicity, but shall have a therapeutic intent". These statements may complicate access to Phase I clinical trials. The law does not explicitly define "therapeutic intent" or "meaningful potential benefit." Consequently, health plans may differ in their interpretation of these phrases. If you are unsure about whether a trial meets these criteria, you may wish to contact the health plan to work out any potential differences of opinion.

If a health plan denies coverage and reimbursement for a patient's care in a study, you will need to go through the health plan's grievance process to appeal the denial. In some cases, you may also need to use California's independent appeal law to try to reverse a prospective or retrospective health plan denial. You can get more information on the independent appeal law from the Department of Managed Health Care (see below).

Issues to consider before enrolling your patient in a clinical trial and seeking health plan coverage and reimbursement…

1. Does your patient meet the patient selection criteria articulated in the protocol?
2. Will participation in the trial offer the patient "meaningful potential benefit" and "therapeutic intent"? Does the medical record reflect that you and the patient have discussed the potential therapeutic benefit of the trial? These entries might help support coverage and reimbursement for Phase I studies.
3. Are you a par or non-par provider with the health plan? If you are non-par, have you contacted the health plan to negotiate your reimbursement rate?
4. Does your patient's health plan require prior approval before enrollment in order the ensure coverage and reimbursement?
5. What portion of the costs is your patient responsible for paying (i.e., copayments and deductibles)?

The clinical trial law states that the protocol must have "meaningful potential benefit to the enrollee" and that the endpoint of the trial "shall not be defined exclusively to test toxicity, but shall have a therapeutic intent".

Conclusions

California's clinical trial law is intended to allow your cancer patients to participate in a Phase I, II, III, or IV clinical trial and receive an investigational therapy in much the same way they would receive a standard therapy. In turn, most health plans must cover the cost of routine patient care services associated with the study. This enhances your ability to prescribe the best possible treatment for your patients.

Questions

In California, two state agencies regulate health plans: the Department of Managed Health Care (DMHC) and the Department of Insurance (DOI). The DMHC regulates prepaid health plans, such as HMOs. The DOI regulates traditional indemnity health plans that are not prepaid. Consequently, if you have a question about the clinical trial law or need help resolving a problem, you will need to contact one of these two agencies. If you have questions about the clinical trial law, how it works, or what it is intended to cover, you can get help from:

Sherrie Lowenstein
Legislative Coordinator and Counsel
Office of Legal Services
Department of Managed Health Care
(see address below)

If you or one of your patients is having a dispute over coverage and reimbursement with a health plan, you can contact:

Department of Managed Health Care
California HMO Help Center
980 Ninth Street, Suite 500
Sacramento, CA 95814-2725
Telephone (General Information): 916-324-8176
Fax: 916- 322-9430
www.dmc.ca.gov
helpline@dmhc.ca.gov

OR:

California Department of Insurance
Consumer Communications Bureau
300 South Spring Street, South Tower
Los Angeles, CA 90013
Consumer hotline: 800-927-4357
www.insurance.ca.gov/docs/index.html
927HELP@insurance.ca.gov

...most health plans must cover the cost of routine patient care services associated with the study. This enhances your ability to prescribe the best possible treatment for your patients.

If you have questions about your patients covered by Medi-Cal, you should contact:

Department of Health Services
Division of Medical Care Services
PHONE: (916) 657-1460
www.medi-cal.ca.gov

ANCO and MOASC extend their thanks to the following professionals and organizations for their help in creating this brochure:

Sandra Bressler
California Medical Association

Richard Figueroa
Office of California Governor Gray Davis

George Fisher, M.D., Ph.D.
Stanford University

Martin Gallegos
California Department of Managed Health Care

Jose Gonzalez, Executive Director,
& the Physician Board of Directors
Association of Northern California Oncologists

David Gandara, M.D. & Primo Lara, Jr., M.D.
University of California, Davis

Mariana Lamb, Executive Director,
& the Physician Board of Directors
Medical Oncology Association of Southern California

Janine MacMillan
National Patient Advocate Foundation

Irene Paulin
Bristol-Myers Squibb Oncology

Richard Steffen
Office of California State Senator Jackie Speier

Margaret Tempero, M.D.
University of California, San Francisco

Debra Thaler-DeMers, R.N.
National Coalition for Cancer Survivorship

This brochure was made possible by an unrestricted educational grant from Bristol Myers Squibb Oncology.

This brochure was researched, written, and edited by Vikram Khanna, Namita Varma, Ph.D., and Pam Barry of State Health Policy Solutions, LLC, of Ellicott City, MD.

© 2003, ANCO, MOASC and State Health Policy Solutions, LLC. All rights reserved. Any unauthorized use of this document, including content changes, without the written permission of ANCO, MOASC, and State Health Policy Solutions, LLC is expressly prohibited.

Association of Northern California Oncologists
P.O. Box 151109
San Rafael, CA 94915-1109
Phone: 415-472-3960
Fax: 415-472-3961

Medical Oncology Association of Southern California
123 East Ninth Street, #202
P.O. Box 161
Upland, CA 91785
Phone: 909-985-9061
Fax: 909-985-8581

State Health Policy Solutions, LLC
8378 Governor Grayson Way
Ellicott City, MD 21043
Phone: 410-480-5277
Fax: 410-480-5278
www.statehealthpolicy.com

Email: vik.khanna
@statehealthpolicy.com