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OPINION	:	No. 86-302
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THE HONORABLE JOHAN KLEHS, MEMBER OF THE CALIFORNIA ASSEMBLY, has requested an opinion on the following question:

May a registered nurse not licensed under the Clinical Laboratory Law lawfully perform a clinitest, acetest, a blood glucose dipstick test, a hematest or hemoccult, or a urine dipstick test in a hospital ward or a medical clinic?

CONCLUSION

When authorized by order of a physician or a standardized procedure a registered nurse not licensed under the Clinical Laboratory Law may lawfully perform a clinitest, acetest, a blood glucose dipstick test, a hematest or hemoccult, or a urine dipstick test in a hospital ward or a medical clinic.

ANALYSIS

We are advised that in some hospitals and clinics registered nurses routinely perform certain tests on specimens taken from patients. These tests include the clinitest, acetest, the blood glucose dipstick test, the hematest and hemoccult, and the urine dipstick test.[1] These tests utilize kits manufactured for each particular test which include a test strip, tablet or solution containing the requisite reagents and a color chart calibrated to give the test results. The specimen is combined with the test strip or solution which produces a color change and the test results are read from the matching color on the color chart. These kit tests may be performed quickly, in close proximity to the patient and without the use of any additional equipment or apparatus.

We are asked whether a registered nurse may perform such kit tests in a hospital ward or a medical clinic. We assume that such tests will be performed on a specimen taken from a patient of a physician in connection with his or her treatment of the patient.

In determining whether a registered nurse may lawfully perform such tests we examine first the authority granted to registered nurses by the Nursing Practice Act (Business and Professions Code section 2700 et seq., the "NPA") and then examine the

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[1] The *clinitest* (reagent strip) and *acetest* (tablet) are used to monitor urine glucose in screenings for diabetes. On contact with a specimen a color change occurs from which an estimate of urine glucose and ketone levels may be made by comparing the test color with a standardized color chart that is supplied with the strips or tablets. (See Physicians' Desk Reference (38th ed. 1984) ("PDR") at pp. 3004, 3008, and 3012.)

Reagent strips also permit a quick determination to be made of the approximate *blood glucose levels* in patients with diabetes. A patch of reagents in a hand-held plastic strip reacts with a capillary blood sample (finger stick) causing a color change which is compared with a standardized color chart providing semi-quantitative readings of blood glucose levels. (See PDR, *supra*, at pp. 3005, 3008.)

The *hematest and hemoccult* are tests for detecting the presence of blood in the feces due to hidden gastrointestinal bleeding. The hematest (reagent tablet) and hemoccult (guaiac filter paper) produce a blue reaction in a fecal smear if a specified amount of blood is present. (See PDR, *supra*, at pp. 3005, 3008, 3016-3017.)

Urine dipsticks are used to test the pH (acidity or alkalinity) of urine or gastric drainage by dipping the reagent strip into a fresh specimen and comparing the resultant color change with a color chart supplied with the test strips. (See PDR, *supra*, at p. 3004.)

Clinical Laboratory Law (§ 1200 et seq., the "CLL") for any provisions which might regulate such testing.

Section 2725[2] in the NPA provides in part:

". . . . . .

"The practice of nursing within the meaning of this chapter means those functions, including basic health care, which help people cope with difficulties in daily living which are associated with their actual or potential health or illness problems or the treatment thereof which require a substantial amount of scientific knowledge or technical skill, and includes all the following:

"(a) Direct and indirect patient care services that insure the safety, comfort, personal hygiene, and protection of patients; and the performance of disease prevention and restorative measures.

"(b) Direct and indirect patient care services, including, but not limited to, the administration of medications and therapeutic agents, necessary to implement a treatment, disease prevention, or rehabilitative regimen ordered by and within the scope of licensure of a physician, dentist, podiatrist, or clinical psychologist, as defined by Section 1316.5 of the Health and Safety Code.

"(c) The performance of skin tests, immunization techniques, and the withdrawal of human blood from veins and arteries.

"(d) Observation of signs and symptoms of illness, reactions to treatment, general behavior, or general physical condition, and (1) determination of whether such signs, symptoms, reactions, behavior, or; general appearance exhibit abnormal characteristics; and (2) implementation, based on observed abnormalities, of appropriate reporting, or referral, or standardized procedures, or changes in treatment regimen in accordance with standardized procedures, or the initiation of emergency procedures. . . .

The rest of the section defines "standardized procedures."

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[2] Section references are to the Business and Professions Code unless otherwise indicated.

In 67 Ops.Cal.Atty.Gen. 122, 137 we construed the basic definition of the practice of nursing (the first quoted of § 2725, above) to include only those functions which are like those specifically enumerated in subdivisions (a), (b), (c), and (d). We therefore examine those subdivisions for authority to perform the tests in question.

Subdivision (b) of section 2725 authorizes a registered nurse to provide "patient care services . . . necessary to implement a treatment . . . regimen ordered by . . . a physician . . . ." The "patient care services" referred to include but are not limited to the administration of medications. We believe that these services include performing one of the tests in question upon a specimen taken from a patient when such testing is ordered by the patient's physician as part of a treatment, disease prevention, or rehabilitative regimen.[3]

Subdivision (d) authorizes registered nurses to make observations of signs and symptoms of illness and reactions to treatment and determine if they are abnormal and based on the observed abnormalities to implement certain procedures in accordance with standardized procedures. We believe that such standardized procedures might well incorporate one or more of the tests in question to assist the nurse to make the observations referred to or to assist in the determination whether they are abnormal.

Subdivision (c) specifically authorizes a registered nurse to perform skin tests among other procedures. It has been suggested that by expressly authorizing the performance of skin tests the Legislature impliedly disqualified registered nurses from performing other kinds of tests. We reject this suggestion because by using the word "includes" to introduce the four subdivisions specifying certain nursing functions the Legislature indicated that the functions specified are not exclusive. (See 67 Ops.Cal.Atty.Gen. 122, 136.)

We conclude that the Nursing Practice Act does provide statutory authority for a registered nurse to perform the tests in question pursuant to the order of a physician to implement a treatment, disease prevention or rehabilitative regimen for a patient or when authorized by a standardized procedure adopted pursuant to subdivision (d) of section 2725.

Turning to the Clinical Laboratory Law we note that unlike other practice acts in the medical arts field the act does not undertake to define the practice being

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[3] We are advised that one use of these tests is to monitor a diabetic patient's need for insulin. The physician may give a standing order to the nursing staff to administer insulin to the patient whenever the patient's blood glucose level reaches a stated level and directs the nurses to perform periodic tests for blood glucose level utilizing an appropriate test kit to determine when the level is reached calling for an insulin shot.

regulated. Instead the CLL in section 1206 defines a "clinical laboratory" as "any place, establishment, or institution organized and operated for the practical application of one or more of the fundamental sciences by the use of specialized apparatus, equipment, and methods for the purpose of obtaining scientific data which may be used as an aid to ascertain the presence, progress, and source of disease in human beings." The CLL then requires licensing of all clinical laboratories with certain exceptions. (See § 1241.) Licensure is also required of all those who work in clinical laboratories with certain exceptions. (See § 1260 et seq.)

Section 1282 of the CLL provides:

> "It is unlawful for any person to make any test or examination *in a clinical laboratory* unless he is a duly licensed physician and surgeon or is duly authorized to do so under the provisions of this chapter." (Emphasis added.)

The words "test or examination" are not defined in the statute. Section 1240 provides in part that the CLL "does not prohibit the performance of tests not covered in Section 1206." Thus the statutory scheme contemplates that not all testing is governed by the CLL.

Section 1220 of the CLL provides that the department (defined in § 1202 to mean the State Department of Health Services) "shall by regulation require that all licensed clinical laboratories maintain records, equipment, and facilities which are adequate and appropriate for the services rendered and demonstrate satisfactory performance in a proficiency testing program approved by the department." The department regulations (tit. 17, Cal. Admin. Code, § 1053) define "clinical laboratory test" and "clinical laboratory specimen" as follows:

> "(a) A "Clinical laboratory specimen" means any material removed from a human being on which examinations can be made to aid in ascertaining the presence, progress, or source of disease in human beings.
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> "(b) Pursuant to the provisions of Sections 1206 and 1240 of the Business and Professions Code a "clinical laboratory test" means a procedure which is performed *in a clinical laboratory* and employs the principles of one or more of the fundamental sciences to detect, identify, measure or enumerate any particular entity or substance in a clinical laboratory specimen." (Emphasis added.)

Both section 1206 and the department regulations expressly restrict the application of the CLL to the "clinical laboratory". Thus if a procedure takes place outside a clinical laboratory the CLL does not regulate it.

The next problem is to determine the meaning of clinical laboratory under the CLL. We start by repeating the statutory definition set forth in section 1206:

> "As used in this chapter, 'clinical laboratory' means any place, establishment, or institution organized and operated for the practical application of one or more of the fundamental sciences by the use of specialized apparatus, equipment, and methods for the purpose of obtaining scientific data which may be used as an aid to ascertain the presence, progress, and source of disease in human beings."

The "place, establishment or institution" language is somewhat vague in defining the perimeter of a clinical laboratory. If a place, establishment or institution is organized and operated solely to make laboratory tests on human specimens the entire facility is a clinical facility under section 1206. A hospital can also be described as a "place, establishment or institution" but it is not organized and operated to make laboratory tests on human specimens. This may be one of its many functions as where a clinical laboratory is established and operated within the hospital. But this fact does not make the entire hospital a clinical laboratory any more than the fact that a separate independent laboratory serves several hospitals and doctor's offices makes those hospitals and doctor's offices clinical laboratories. The statutory definition confines a clinical laboratory to the place where there is a "practical application of one or more of the fundamental sciences by use of specialized apparatus, equipment and methods for purposes of obtaining scientific data which may be used as an aid to ascertain the presence, progress, and source of disease in human beings." This language contemplates that a clinical laboratory will have specialized apparatus and equipment and that methods involving the practical application of one or more of the fundamental sciences utilizing such apparatus and equipment will be used to obtain certain scientific data useful in diagnosing and treating human diseases. We will refer to these methods as "laboratory testing."

Section 1220 of the CLL contemplates that a clinical laboratory is to have certain attributes in addition to those specified in section 1206. Section 1220 provides:

> "The department shall by regulation require that all licensed clinical laboratories maintain records, equipment, and facilities which are adequate and appropriate for the services rendered and demonstrate satisfactory performance in a proficiency testing program approved by the department. In addition, the department shall by regulation require that all licensed

clinical laboratories be conducted, maintained, and operated without injury to the public health."

The department has adopted regulations pursuant to section 1220 which are set forth in title 17, California Administrative Code, section 1050. Subdivision (d) of these regulations provides that there must be adequate space to conduct and control all tests performed in the laboratory. Subdivision (e) states that the laboratory must provide for and assure that equipment, instruments, glassware, and reagents are maintained in proper working order by periodic inspection, testing or calibration. Subdivision (c) requires that some person be responsible for directing the operations of the clinical laboratory. Subdivision (f) requires that a clinical laboratory must maintain records of specimens received and tested, records of inspections, and written descriptions of each procedure used. Thus the CLL and the implementing regulations confine a clinical laboratory to a place which has specified attributes in which laboratory testing on human specimens is done.

Section 1288 in the CLL provides in part that "[a]ny person conducting or operating a clinical laboratory may accept assignments for tests only from and make reports only to persons licensed under the provisions of law relating to the healing arts or their representatives." Subdivision (f) of the regulations (tit. 17, Cal. Admin. Code, § 1050) requires a clinical laboratory to maintain records of specimens received and tested, including identification of the patient, name of the submitter, dates of receipt and report, type of test performed, and test results. Subdivision (h) of the regulations provides that clinical laboratory test results shall not be reported from the laboratory until these results have been critically reviewed and verified for accuracy, reliability, and validity by a physician or a person, other than a trainee, licensed under the CLL. Thus the CLL contemplates that physicians will have specimens taken from their patients, send the specimens to a clinical laboratory and receive reports back of the test results.

A physician may have reasons to have an immediate test made on a specimen taken from his or her patient rather than send the specimen out to a clinical laboratory. The most obvious reason is speed. It may take too long to send the specimen to a clinical laboratory and await the report of test results to be useful. A faster (though perhaps less accurate) test may better suit the patient's needs. Another reason may be cost. A bedside test without the packaging, labeling, transport, review and report writing required in laboratory testing may well be less costly.

When the applicability of the CLL to the tests in question is considered several questions arise. Is a hospital ward or medical clinic a clinical laboratory within the meaning of the CLL? Are the kit tests in question the kinds of procedures the CLL was intended to regulate? Does the CLL limit the authority granted to registered nurses by the NPA? These questions will be considered in turn.

We are asked whether a registered nurse may lawfully perform certain kit tests in a hospital ward or medical clinic. We have seen that the CLL governs only those procedures which take place "in a clinical laboratory." We reject the suggestion that any place where the testing of human specimens to aid in ascertaining the presence, progress or source of disease occurs is a clinical laboratory under the CLL because such an interpretation is at odds with the definition and attributes of a clinical laboratory as contemplated in the statute and its implementing regulations. Ordinarily a hospital ward or medical clinic does not contain or have the attributes of a clinical laboratory. They do not have the laboratory equipment and apparatus, reagents and glassware needed to make many tests, nor is the requisite equipment and procedure testing and record keeping done there. Conceivably a clinical laboratory with the requisite equipment, staffing, record keeping and licensure could be set up in a hospital ward or medical clinic[4] but we do not think that is what was contemplated by the question. We conclude that the ordinary hospital ward and medical clinic is not a clinical laboratory within the meaning of the CLL.

As previously noted the tests in question all utilize a kit manufactured to provide all the materials necessary to perform and evaluate a particular test. No other equipment or apparatus of the kind found in a clinical laboratory is needed. It is not necessary to take the specimen to another place for testing and obtain a report of the results. The tests in questions may be performed at the bedside of the patient with results immediately available to those administering to the patient's medical needs. While the materials provided in the test kits are the product of a practical application of one or more of the fundamental sciences, such practical application is accomplished by the kit manufacturer not by the person performing the test. A detailed knowledge of biology and chemistry is needed to select and create the special reagent tablet, liquid, or impregnated dipstick which will produce the particular chemical reaction needed to produce the color change or other indication to detect and/or measure the questioned substance in a specimen. However, neither laboratory apparatus nor expertise in analysis is necessary to perform the kit test in question. All of the chemistry and the expertise to make the test work have been built into the test kit. A nurse performing one of these kit tests need not be versed in the biochemical detail and scientific basis of the test any more than a person using a Polaroid

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[4] If a clinical laboratory is established in a hospital ward or a medical clinic may a registered nurse perform the subject tests therein? This question requires an examination of the purpose for which the nurse makes the test. If the nurse is employed to perform any part of the laboratory testing which occurs in such clinical laboratory then he or she must have the licenses required for such functions by the CLL. However, if the nurse's performance of the test in question is not part of any laboratory testing as contemplated in section 1206 (e.g., the nurse is carrying out a physician's order to make such test as part of a patient's treatment regimen), the fact that the test is done in the clinical laboratory would not subject the nurse to the licensing requirements of the CLL.

camera needs to be versed in the intricacies of photography and film developing in order to take and have instant photographs. Technology has provided the means to perform certain tests on human specimens without resort to a clinical laboratory. Thus we believe that the kit tests in question are not the kinds of procedures which the Legislature intended to regulate in the CLL.

Section 1240 provides in part that the CLL "does not repeal or in any manner affect any provision of this code relating to the practice of medicine." The tests referred to in the question are made in a hospital ward or medical clinic. We have assumed they are performed on specimens taken from patients as an aid in the treatment of the patient by the patient's physician. Under such circumstances the performance of such tests would be part of the treatment of the patient by the physician and thus part of the physician's practice of medicine. Under the express language of section 1240 the CLL does not in any manner affect provisions of the code relating to the practice of medicine.

For these reasons we conclude that a registered nurse not licensed under the CLL may lawfully perform a clinitest, acetest, a blood glucose dipstick test, a hematest or hemoccult or a urine dipstick test in a hospital ward or a medical clinic when ordered by a physician or authorized by a standardized procedure.

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