Original: 2119

PENNSYLVANIA
SCHOOL BOARDS
ASSOCIATION, INC.

774 LIMEKILN ROAD, NEW CUMBERLAND, PA 17070-2398 / (717) 774-2331 / FAX (717) 774-0718

June 26, 2000

Robert E. Nyce, Executive Director
Independent Regulatory Review Commission
Commonwealth of Pennsylvania
333 Market Street
14th Floor
Harrisburg, PA 17101

Dear Mr. Nyce,

Enclosed are the comments of the Pennsylvania School Boards Association to the Department of Health concerning proposed revisions to Title 28, Part II, Chapter 27, on communicable and noncommunicable diseases, that was published in the May 27, 2000 issue of the *Pennsylvania Bulletin*. Our comments focus on changes that will affect children and staff in school settings.

Generally, we are supportive of the proposal that extends the requirements under the existing regulation to school staff as well as students. However, we believe that there are a few issues within the proposal that need to be clarified. We recommend that the department establish a definition of "school employee" that would clearly state what personnel must comply with the provisions, as well as indicate who does not have to comply. We also suggest that volunteers in schools be specifically excluded from the requirements and that language, if so necessary, simply state that school officials have the authority to prohibit volunteers from working with students and employees if it is believed that a health risk exists.

We also suggest that the proposal clearly state that a school nurse *or* physician is equally able to determine if an employee or student may be readmitted to school. Most schools do not have a nurse in the building every day; in addition, the function of school nurses is to focus on the health of students, not employees, on a routine basis. Finally, we urge the department to clarify new recordkeeping duties for schools and develop guidelines and forms to assist them with this task.

We offer these comments to you as the proposal moves through the regulatory review process. Please contact me if you have any questions regarding the issues addressed in this letter.

Sincerely,

Thomas J. Gentzel
Assistant Executive Director
Governmental and Member Relations

Original: 2119

The City of YORK PENNSYLVANIA

Mayor Charles H. Robertson

DIVISION OF COMMUNITY AFFAIRS

Director's Office
849-2292

Health
849-2252

Housing Services
849-2264

Planning & Zoning
849-2307

Permits/Licensing
849-2256

DIVISION OF PUBLIC SERVICES

Director's Office
849-2245

Building/Electrical Maintenance
845-9351

Environmental Services
849-2245

Highway Maintenance
849-2320

Recreation & Parks
854-1587

June 15, 2000

James T. Rankin, Jr., D.V.M, M.P.H., Ph.D.
Director
Division of Communicable Disease Epidemiology
Pennsylvania Department of Health
P.O. Box 90
Harrisburg, PA 17108

Dear Jim:

Attached are comments and suggestions submitted by me in regards to the proposed amendments to the regulations on reporting of communicable and noncommunicable diseases as published in the Pennsylvania Bulletin, Volume 30, Number 22, Saturday, May 27, 2000. Your consideration of the comments and suggestions is greatly appreciated.

Sincerely yours,

David L. Hawk, M.D., M.P.H.
Director
York City Bureau of Health

Enclosure (1)

Comments on Proposed Revision to Annex A. Title 28. Health and Safety. Part III. Prevention of Diseases. Chapter 27. Communicable and Noncommunicable Diseases.

Subchapter A. General Provisions
§ 27.1 Definitions.
p. 2729-30: *Health care facility—*
(ii) The term does not include:
(A) An office used primarily for the private practice of a health care practitioner where no clinically related health service is offered.

I don't understand what this means. A definition of "clinically related health service" is necessary to clarify this.

Local health authority—
...The term does not include a sanitary board.

Are sanitary boards included under some other definition? If not, a definition of sanitary board should be included.

Local health department—
...The Department will maintain a list of local health departments and revise the list when new local health departments are established.

Or when currently existing local health departments are closed?

Modified quarantine—
and
Quarantine—
(i) Segregation—

These definitions are repeated on page 2731.

p. 2731:
(ii) *Surveillance—*

This definition is repeated under "Surveillance of contacts" below.

The term "surveillance" has two different meanings (surveillance of contacts and surveillance of disease) which is confusing. Perhaps the former could be called something else (e.g., monitoring of contacts)?

p. 2733:
§ 27.6 Disciplinary consequences for violating reporting responsibilities.

There is no reference in this section to disciplinary consequences for child care group settings. I believe the Department of Public Welfare's regulations for licensure of these facilities cover this.

p. 2733-4:
§ 27.21a. Reporting of cases by health care practitioners and health care facilities.
(a) The following diseases...are reportable...within the specified time periods:
(1) The following diseases...are reportable within 24 hours...
...Haemophilus influenzae type B invasive disease

Delete "type B" — all H. influenzae invasive disease is nationally reportable and many clinical laboratories do not conduct serotyping. Even those that do may not have the results available for several additional days, but action may need to be taken sooner.

Hepatitis, viral, including type A and type E

Delete "including" — the other types of viral hepatitis are included in the next section (reportable within 5 business days).

To this list, add:

Anthrax
Animal bite**
Arbovirus disease**
Enterohemorrhagic E. coli**
Legionellosis**
Small pox (Variola)*

*due to possible bioterrorist attack ** action needs to be taken in less than five days

(2) The following diseases...are reportable within 5 work days...

Hepatitis, viral, including type B, type C, type D, type G

Delete "type G" which does not exist and add "Non A, Non B"

Delete the following (which should be moved to section (1) above):

Animal bite
Anthrax
Arbovirus disease
Enterohemorrhagic E. coli

Add:

Creutzfeld Jacob disease
Streptococcus pneumoniae, Drug-Resistant Invasive Disease
Staphylococcus aureus, Vancomycin-Resistant (or Intermediate) Invasive Disease

p. 2734:

§ 27.22 Reporting of cases by clinical laboratories.

(b) The diseases...to be reported include:

Arboviruses limited to Eastern, Western, and St. Louis encephalitis

Delete "limited to," add "Equine" after both "Eastern" and "Western," and add "West Nile" after "St. Louis."

As New York's recent experience with West Nile Virus indicates, other arboviruses may appear in unexpected places and should be reported. Any arboviral encephalitis case could lead to mosquito control efforts and other public health actions.

Haemophilus influenzae type B in fections—invasive from sterile site

Delete "type B" (see comments above) and remove space between "n" and "f" in "infections."

Hepatitis, viral, including types A, B, C, D, E and G

Delete "and G" (which does not exist).

Add:

Creutzfeld Jacob disease
Streptococcus pneumoniae, Drug-Resistant Invasive Disease

Staphylococcus aureus, Vancomycin-Resistant (or Intermediate) Invasive Disease

p. 2735:
(c) The report shall include the following:

Add: source of specimen (e.g., serum, CSF, stool, wound)
results
range of normal values for the specific test

p. 2739:
§ 27.43a. Reporting by local morbidity reporting offices of outbreaks and selected diseases.
(4) Other reportable diseases and conditions.
(b)
There is no "(a)"

(2) Anthrax, botulism, cholera, enterohemorrhagic E. coli, hantavirus pulmonary syndrome, hemorrhagic fever, hepatitis A, hepatitis E, human rabies, meningitis, plague, typhoid fever, and yellow fever.

Delete hepatitis A and meningitis. Add "foodborne" before "botulism."
Add:
Arbovirus disease**
Haemophilus influenzae invasive disease in a child under 15 years of age**
Legionellosis**
Smallpox*

*due to possible bioterrorist attack ** action needs to be taken in less than five days

p. 2741:
§ 27.67. Movement of persons and animals subject to isolation or quarantine...
(d) ...The sender, the receiver and the transporter of the animal shall be responsible...

Add "person or" before "animal."

p. 2742-3:
§ 27.71 Exclusion of pupils and staff for specified diseases and infectious conditions.
A person in charge of a...school or college shall exclude from school a pupil, or a staff person ...having any of the following:

Add:
(16) *Neisseria meningitidis invasive disease.* Until made noninfective by a course of rifampin or other drug which is effective against the nasopharyngeal carriage state of this disease, or otherwise shown to be noninfective.

This is already included in § 27.76 for child care group settings, but is equally applicable for schools.

p. 2743:
§ 27.76. Exclusion and readmission of children and staff in child care group settings.
(8) Exposure to an individual with invasive H. influenza disease...

Should be "influenzae," but there is no reason to exclude these children or staff members from the child care group setting. This section should be deleted.

(9) Exposure to an individual with meningococcal disease.

There is no reason to exclude these children or staff members from the child care group setting. This section should be deleted.

p. 2748:
§ 27.98. Prophylactic treatment of newborns.

Add "or if in the opinion of the attending physician the treatment is not advisable" before "prophylactic treatment shall be withheld."

§ 27.99. Prenatal examination for hepatitis B.
(b) ...If the parent or guardian...objects...prophylactic treatment shall be withheld.

This sentence should be deleted. No parent has ever expressed a religious objection to this treatment (which is not really "prophylactic" but rather is treating the infant's exposure to the mother's hepatitis B in order to prevent chronic disease in the baby), and it seems likely that such an objection could be challenged in court.

Subchapter E. SELECTED PROCEDURES FOR PREVENTING DISEASE TRANSMISSION
§ 27.151. Restrictions on the donation of blood, blood products, tissue, sperm and ova.
(a) A person known to be infected...is not allowed to donate...

Add "or suspected" after "known."
Confirmation of the person's infection may take days to months, and in the interim, the organs or tissue might have been donated.

(b) In addition, a person or entity may not accept any of these materials for donation without obtaining laboratory evidence showing the absence of...

Add "from a person known or suspected of being infected with the causative agent of a reportable disease" before "for donation" and "and" before "without obtaining."
If the donor who has the infection is prohibited from donating, the recipient agency should also be prohibited from accepting the donation. Although the screening tests will prevent donations from persons who are carrying hepatitis B, hepatitis C, or HIV, none of the other reportable diseases would be detected.

p. 2748-9:
§ 27.153. Restrictions on food handlers.
(4) *Typhoid fever or paratyphoid fever*...nor earlier than 48 hours after receiving the last dose of a chemotherapeutic drug effective against Salmonella typhi...

Add "or paratyphi" after "typhi."

§ 27.154. Restrictions on caregivers in a child care group setting.
(4) *Typhoid fever or paratyphoid fever*...nor earlier than 48 hours after receiving the last dose of a chemotherapeutic drug effective against Salmonella typhi...

Add "or paratyphi" after "typhi."

§ 27.153. Restrictions on health care practitioners.
(4) *Typhoid fever or paratyphoid fever*...nor earlier than 48 hours after receiving the last dose of a chemotherapeutic drug effective against Salmonella typhi...

Add "or paratyphi" after "typhi."

p. 2751:
Subchapter F. MISCELLANEOUS PROVISIONS
PSITTACOSIS

§ 27.183. Occurrence of psittacosis.

Add:
(c) A bird with psittacosis that has been placed under quarantine may not be sold or removed from its isolation quarters until it has been treated for at least seven days. After seven days, it may be sold, but the buyer must be made aware in writing with a signed receipt of the significance of psittacosis and the signs and symptoms to look for. The signed receipt paperwork will include a copy of any documents provided the new owner and will be maintained at the place of sale for six months after the sale of the quarantined bird. The duration of additional treatment necessary must be established at the time of sale and a supply of medicated feed sufficient for the duration of treatment must be provided to the new owner.

p. 2752"
DISPOSITION OF EFFECTS AND REMAINS OF INFECTED PERSONS
§ 27.201. Disposition of articles exposed to contamination.
...bubonic plague or anthrax...

Add ", smallpox (variola)," before "anthrax."
This was deleted, but should be retained due to the potential use of this agent by terrorists.

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

June 23, 2000

Mr. John McGinley, Jr.
Chairperson
Independent Regulatory Review Commission
333 Market Street
14th Floor
Harrisburg, PA 17101

RE: Title 28. Health and Safety, Part III. Prevention of Diseases, Chapter 27. Communicable and Noncommunicable Diseases

Dear Mr. McGinley:

The Hospital & Healthsystem Association of Pennsylvania (HAP), on behalf of its approximately 250 member institutions, comprised of 125 stand-alone hospitals and another +120 hospitals that comprise 32 health systems across the state, welcomes the opportunity to comment on the proposed regulations dealing with the communicable and noncommunicable disease reporting and control of disease transmission. HAP commends the Department of Health for tackling the job of updating this set of regulations. HAP would like to bring the following concerns and/or recommendations to the attention of the Department of Health:

Subchapter A. General Provisions

- HAP encourages the Department of Health to simplify its definition of outbreak. Specifically, outbreak should be defined as the excess of the expected incidence of disease within a particular geographic area or population in a specified time period. This definition is found in the *Epidemiology Handbook* published by the Association for Professionals in Infection Control and Epidemiology (APIC).

- § 27.6 outlines the disciplinary consequences that might occur if a clinical laboratory, licensed health care facility or health care practitioner fails to comply with the disease reporting requirements. Given the complexities of accurate disease reporting, the Department of Health should consider modifying this section to indicate that disciplinary consequences may result, if there is evidence of willful violation of disease reporting requirements or a demonstrated pattern of noncompliance on the part of a clinical laboratory, licensed health care facility or health care practitioner.

- § 27.8 provides for criminal penalties against persons who violate the provisions outlined in this chapter, including persons with tuberculosis placed in isolation who leave an organization against medical advice. HAP believes that the

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imposition of fines and possible imprisonment of isolated patients with tuberculosis will not serve as a deterrent to such behavior, especially if the individual is destitute or homeless and that such a regulation will neither be enforceable nor is in the best interest of quality patient care. Hospitals have described a series of issues that they confront when such an individual leaves their organization against medical advice. Hospital staff and security cannot detain these individuals. Alternatively, when hospitals report such occurrences to law enforcement authorities, they indicate that law enforcement officials will not detain or arrest these individuals. Furthermore, it is unclear whether such incidents should be brought to the attention of local or state health authorities for possible intervention. HAP recommends that the Department of Health provide some guidance that outlines the procedure that providers should follow when a patient under their care and covered under the provisions of these regulations leaves their organization against medical advice.

- Hospitals also have voiced concerns with the extended periods of time that acute care hospitals are being used to essentially house tuberculosis patients that require isolation or are non-compliant with therapy. Although isolation or monitoring of compliance with medication therapy may be necessary from a public health standpoint, the stay in an acute care hospital may be determined not to be medically necessary by the payor. In these situations, acute care facilities are being asked to house tuberculosis patients without the benefit of reimbursement at the level needed to care for those patients. HAP recommends that the Department of Health and/or local health authorities develop alternative placement arrangements for tuberculosis patients who no longer require the services of an acute care hospital. Alternatively, the issue of reimbursing hospitals for the provision of such services needs to be addressed by the Department of Health with governmental and commercial payors.

- §27.9 provides the Department of Health to make exceptions to any regulation in Chapter 27 should the regulation become outdated due to medical and public health developments provided the exception does not violate statutory requirements. §27.9 further states that exception will not remain in effect for more than 90 days unless the Board acts to affirm the exception within that 90-day period. HAP has concerns with this process in that it is unclear how the Department of Health would make public what exception(s) have been made to existing regulations and what authority the Advisory Health Board has to make such exceptions permanent without formally subjecting such changes to the regulatory review process. HAP noticed that the Department of Health excluded similar language in other sections of these proposed regulations that originally appeared in the draft regulations circulated for stakeholder comment. HAP

questions whether the Department of Health wanted to maintain this language in the proposed regulations, especially since "Board" is not defined in an earlier section of the proposed regulations.

Subchapter B. Reporting of Diseases, Infections and Conditions

- In §27.21, the Department of Health places the reporting of AIDS cases solely with physicians. Hospitals identified several different ways and professionals that were responsible for AIDS reporting at their facilities. Nurse practitioners running nurse-based clinics, nurse practitioners or other clinicians in physician offices, or nurse managers and other clinicians involved in hospital-based AIDS clinics often assume the responsibility for reporting AIDS cases to the appropriate health authority. HAP has considerable concern that this regulation as written will result in significant underreporting and suggests that AIDS be included in the reportable list of diseases by health care practitioners and health care facilities. In this way, each organization can best determine who should retain responsibility for the reporting of various diseases, including AIDS. HAP is also concerned with the possible underreporting of AIDS cases since funding for various AIDS-related prevention and intervention programs has traditionally been related to the volume of reported cases in each state.

- In comparing the list of diseases that must be reported by health care facilities and health care practitioners and the list of diseases that must be reported by clinical laboratories, HAP suggests that the department consider making the following changes:

  (1) include crytosporidiosis, histoplasmosis, meningitis, toxoplasmosis, and yellow fever on the list of reportable diseases for clinical laboratories;

  (2) list arboviruses in the same manner in both the clinical laboratories list and the health care facilities list of reportable diseases, including naming the various arboviruses that need to be reported – eastern encephalitis, western encephalitis, St. Louis encephalitis and yellow fever;

  (3) change the placement of hepatitis reporting in the health care facilities list to make all types of hepatitis reportable within 5 working days after being identified and indicate that hepatitis, viral, including types A, B, C, D, E and G be reported;

(4) remove respiratory syncytial virus from the clinical laboratories list of reportable diseases as there was the strong sense that local health authorities would be inundated with these reports and the Department of Health has not identified the purpose of adding this particular disease to the list of reportable diseases in its preamble;

(5) clarify what the Department of Health expects to be reported by its identification of an "unusual cluster of isolates" in the list of reportable diseases by clinical laboratories since the term "unusual" may mean something different depending upon the type of disease; and

(6) remove varicella (chickenpox) from the reportable disease list for health care facilities and health care practitioners until the Department of Health determines whether such reporting is warranted based upon trends in the information initially reported by clinical laboratories. By including a three-year time frame, the department already presupposes that varicella cases will need to be reported by health care facilities and practitioners. Further, HAP suggests that the reporting of varicella by health care facilities and practitioners be delayed until such time that varicella immunization is a required vaccine for entry into school. Although the department has indicated that health care facilities and practitioners would not need to report varicella cases until three years after the adoption of these regulations, there is the possibility that varicella vaccination may still not be a required vaccination by that time. It is HAP's understanding that the Department of Health would like to understand the efficacy rate of the varicella vaccine. Therefore, it seems appropriate that health care facility and practitioner reporting of such cases should not occur until such time that the vaccine becomes mandatory for admittance to school.

- § 27.21(b)(1) indicates that a health care facility or health care practitioner is not required to report a case if that health care practitioner or health care facility has reported the case previously. HAP requests that the department consider clarifying that a health care facility is not required to report a case if the facility's clinical laboratory has already reported the case. Hospitals have indicated that they do not report a case if their clinical laboratory has already reported that case to local or state health care authorities.

- The regulations as proposed by the Department of Health indicate that health care facilities or practitioners need to report diseases to the local health care authority in which the patient resides. We believe it would be much easier to contact their local health authority to provide the relevant case information,

rather than having each organization try to determine which local health authority they should be reporting that information to in Pennsylvania. The local health authority could in turn determine where to appropriately refer that case information. Many hospital infection control practitioners indicated that this is how they are currently handling case reports for those patients who reside in another county or city that has its own health department.

- In reviewing all of the various requirements where case reports for various diseases should be relayed, it quickly becomes apparent that there are many reasons why reports are not filed with appropriate agencies. For instance, a health care facility and practitioner must report cases of sexually transmitted diseases to the appropriate health authority of the county or municipal health department when the patient resides in a city or county that has its own health department. Otherwise, these reports need to be transmitted to the Division of Tuberculosis and Sexually Transmitted Diseases, Bureau of Communicable Diseases, Department of Health. Alternatively, reports of metabolic diseases, including maple syrup urine disease, phenylketonuria, primary congenital hypothyroidism and sickle cell hemogloinopthies do not need to be reported to local or municipal health authorities, but do need to be directed to yet another bureau, the Division of Maternal and Child Health, Bureau of Family Health. There are other requirements for reporting lead poisoning and other diseases. HAP strongly recommends that the Department of Health consider ways to simplify its disease reporting requirements possibly by creating a clearinghouse where reports could be submitted by health care facilities and practitioners that could in turn be transmitted to all the relevant agencies that need that information. In the meantime, HAP recommends that the Department of Health create easy to use one-page laminated reference sheets that permit health care facility personnel and practitioners to identify where disease reports should be transmitted.

Subchapter C. Quarantine and Isolation; Communicable Diseases in Children and Staff Attending Schools and Child Care Group Settings

- It appears that this subchapter is intended to deal with the quarantine and isolation of persons in the community, particularly since the Department of Health deleted an existing section, titled isolation within hospitals. HAP requests the Department of Health clarify the intent of this subchapter as it relates to hospitals in the regulation's preamble or indicate in the regulations under what circumstances health care facilities need to contact local health officials to confer about matters related to quarantine and isolation. Hospitals routinely adhere to

Centers for Disease Control (CDC) standards related to isolation of patients and the transporting of those patients throughout the health care facility or other health care facilities in and outside of Pennsylvania without involving local or state health officials. HAP does not believe that the Department of Health needs to get calls from hospitals on matters related to isolation that are considered routine.

- HAP requests that the department reconcile differences in its regulations dealing with exclusion of students and staff from attending schools and child care settings with the CDC Personnel Health Guidelines published in the September 8, 1997 *Federal Register* (Volume 62, pages 47275-47320) that deal specifically with the prevention of nosocomial transmission of selected infections. In reviewing the Department of Health regulations and the CDC guidelines, there are considerable differences in the length of time persons should be restricted from returning to school or child care, in how asyptomatic exposed personnel should be managed or in how exposed persons without disease immunity should be handled. The same CDC Personnel Health Guidelines can also be found in the *American Journal of Infection Control* (Volume 26, pages 289-354). HAP did forward these guidelines to the Department of Health when comments to the stakeholder draft were submitted for the Department of Health's consideration.

Subchapter D. Sexually Transmitted Diseases, Tuberculosis and Other Communicable Diseases

- HAP continues to have serious concerns about §27.97, which deals with the treatment of minors. The current regulations allow for a person under the age of 21, infected with a venereal disease (sexually transmitted disease), to be given appropriate treatment by a physician without the consent of his/her parents or guardian. The proposed revisions significantly broaden the intent by allowing for any individual under 21 years of age to give consent for medical and other health services to determine the presence of or to treat a sexually transmitted disease and any other reportable disease, infection or condition without another person's consent. As written, this would mean that a minor could give consent for the diagnostic workup of suspected cancer and cancer treatment without parental consent. First, there is obvious concern whether minors of a certain age can appropriately give informed consent to diagnosis, evaluation and treatment. Second, health care facilities and practitioners do not engage and are not likely to engage in the care of minors without obtaining informed consent from the minor's parent or guardian. Third, the original regulations were developed in a different cultural climate where there was a significant stigma attached to the acquisition of a venereal disease to the point where individuals did not seek treatment. While HAP recognizes the Department of Health's need to address an individual's

access to health care services for the treatment of diseases that threaten the public's health, the Department of Health also needs to be cognizant of parental rights and responsibilities in consenting to the provision of health services to children and adolescents. HAP again requests that this section undergo further legal review since it has been made exceptionally broad in allowing for evaluation and treatment of all reportable diseases, infections or conditions in a minor without parental consent and seems to ensure immunity to a practitioner if he/she evaluates and treats a minor with a reportable disease, infection or condition without parental consent.

Subchapter E. Selected Procedures for Preventing Disease Transmission

- HAP again requests that the Department of Health reconcile differences in this subchapter dealing with §27.153 restrictions on food handlers, §27.154 restriction on caregivers in a child care setting, and §27.155 restriction on health care practitioners with the CDC Personnel Health Guidelines published in the September 8, 1997 *Federal Register* (Volume 62, pages 47275-47320) that deal specifically with the prevention of nosocomial transmission of selected infections. In particular, HAP asks that the Department of Health reconcile the discrepancies with respect to hepatitis A and diarrhea, including the fact that use of the term itself may be outmoded and should be replaced by using the term gastroenteritis.

- As mentioned previously, Department of Health requirements related to special requirements for measles, §27.160, should also be reconciled for discrepancies with the aforementioned CDC Personnel Health Guidelines.

HAP strongly suggests that the Department of Health provide education sessions across the state about disease reporting, particularly since there are differences in how various county health departments or other local health authorities work with health care facilities and practitioners in disease reporting, the presence or absence of county health departments dictates the manner in which diseases are reported, and the special requirements for the reporting of certain diseases, infections or conditions that exist. It would be beneficial if the Department of Health could discuss its plans, if any, for electronic submission of reports, review the forms used for disease reporting, and provide reporting contacts and phone numbers for each county as appropriate to assist health care facilities, health care practitioners and clinical laboratories in fulfilling their reporting requirements as outlined in the regulations. HAP also requests that the Department of Health give consideration to including a hospital-based infection control practitioner on department task forces or the Advisory Health Board of the department to ensure that the organization perspective related to disease surveillance is considered, and appropriately addressed.

Again, HAP appreciates the opportunity to comment on the Department of Health's proposed regulations addressing the reporting of communicable and noncommunicable diseases and the Department of Health's efforts in attempting to significantly revise and update these regulations. HAP believes that our suggestions and recommendations will improve or clarify the revisions that the Department of Health is proposing be made to the existing set of regulations. HAP looks forward to working with the Department of Health in areas of infection control and epidemiology to benefit community health and protect the public from harmful diseases or infections.

If you have any questions about the issues or suggestions outlined in this letter, please feel free to contact Lynn Gurski-Leighton, Director, Clinical Services, HAP at 717-561-5308 or by email at lgleighton@hap2000.org.

Sincerely,

Paula A. Bussard

PAULA A. BUSSARD
Senior Vice President, Policy and Regulatory Services

PAB/zf

c: Howard A. Burde, Esq., Deputy General Counsel, Office of General Counsel
Helen K. Burns, Deputy Secretary for Health Planning and Assessment, DOH
Vincent J. Hughes, Minority Chair, Senate Public Health & Welfare Committee
Lori McLaughlin, Esq., Chief Counsel, Department of Health
Harold F. Mowery Jr., Chair, Senate Public Health & Welfare Committee
Dennis M. O'Brien, Chair, House Health & Human Services Committee
Frank L. Oliver, Minority Chair, House Health & Human Services Committee
James T. Rankin, Jr., DVM, MPH, PhD

Original 2119

June 26, 2000

VIA FACSIMILE (772-6975)
AND U.S. MAIL

James T. Rankin, Jr., D.V.M., M.P.H., Ph.D.
Director, Div. of Communicable Disease Epidemiology
Department of Health
P.O. Box 90
Harrisburg, PA 17108

Re: Department of Health Proposed Regulations:
Reporting of Communicable and Non-Communicable Diseases

Dear Dr. Rankin:

The Pennsylvania Academy of Family Physicians (the "Academy") represents over 4,500 physician members. The following comments are submitted in response to the Department of Health's proposed regulations related to the reporting of communicable and non-communicable diseases, which were published at 30 *Pa. Bulletin* 2715-2752 (May 27, 2000).

The Academy applauds the Department for its fine work in updating and formatting the new regulations consistent with current public health concerns and health care priorities. The comments that follow outline a few substantive, procedural and technical concerns which the Academy has identified.

Education Rather Than Discipline - § 27.6(c)

Although the Academy understands the Department's concern that all identified diseases that impact public health be properly reported, the Academy can find no legislative authority for the Department's threat that disciplinary action may be taken against an individual health care practitioner's license as a result of a failure to report in any particular instance. The provision should be deleted in final rulemaking.

The Department has disciplinary authority over health care facilities and clinical laboratories. However, neither the Disease Prevention and Control Law of 1955 ("DPCL"), under which the regulations are promulgated, nor any other applicable law, authorizes the Department to impose discipline on an individual health care practitioner's

license, nor is the Department authorized to insert itself into that process. A regulatory provision such as this, which is not grounded in legislative authority, would be null, void and unenforceable. Pennsylvania Medical Society v. State Board of Medicine, 546 A.2d 720 (Pa. Cmwlth. 1988). The Department's enforcement authority is adequate as set out in § 27.8, which accurately tracks the permissible enforcement provisions of the DPCL.

Alternatively, the Academy recommends that the Department focus on providing, to persons and entities required to report, educational information concerning specific reporting procedures, reportable diseases, infections and conditions and the consequences both for individuals and the public health when reporting requirements have not been met. In this way, reporters will have a positive incentive to continue to comply with the provisions of the regulations.

Coordination of Multiple Reporting - §§ 27.21a, 27.22, 27.23

The Academy questions the need for potentially overlapping reporting of the same diseases, infections and conditions by health care practitioners, health care facilities, clinical laboratories and individuals in charge of group facilities. To the extent the Department needs multiple reporting, the Academy requests that the Department specify how the reporting can be coordinated among practitioners, laboratories and facilities, all of whom may be required to report with respect to the same patient.

Unique Identifier Number - §§ 27.22(c), 27.31(c), 27.34(i), 27.5a

The information required on reports from laboratories includes the name of the person from whom a specimen has been obtained, his or her address and telephone number. All medical records of cancer patients are open and accessible to the Department and/or its agents. All lead poisoning reports require that the name of the patient be included. Although the confidentiality of case reports is anticipated once in the hands of the Department, the information from the reports can be released under certain circumstances within the discretion of the Department or the local morbidity reporting office.

The Academy recommends that the Department adopt a Unique Identifier Number ("UIN") system such that all reports will remain utterly confidential, yet permit the Department to fulfill its obligations under the law in respect to safeguarding the public health and safety. The Academy notes that other states have adopted a UIN system for such purposes which appears to be working quite well.

HIV/AIDS Reporting - § 27.21

A "communicable disease" is defined under the proposal as "an illness which is capable of being spread to a susceptible host through the direct or indirect transmission of an infectious agent or its toxic product by an infected person, animal or arthropod, or through the inanimate environment." 28 Pa. Code § 27.1. Likewise, an "infectious agent" is defined as "an organism, such as a virus, bacterium, fungus or parasite, that is capable of being communicated by invasion and multiplication in body tissues and capable of causing disease." 28 Pa. Code § 27.1.

The Human Immunodeficiency Virus (HIV) falls squarely within these definitions as does Acquired Immune Deficiency Syndrome (AIDS). Indeed, a more deadly communicable disease or infectious agent does not currently exist. The Academy questions why the Department has not included HIV as a reportable "disease, infection or condition." Indeed, the Legislature, pursuant to the Confidentiality of HIV-Related Information Act, has contemplated the reporting of HIV-related information under the DPCL. 35 P.S. § 7607(a)(9).

Symptoms Warranting Exclusion of Pupils and Staff - § 27.72(a)(7)

The Academy suggests that "diarrhea" be included as a symptom permitting the temporary exclusion of a pupil or a staff person from a school or college to the extent the person may represent a communicable disease risk to the school population. Accordingly, § 27.72(a)(7) would read, "Vomiting or Diarrhea." With the addition of this symptom, the language would be consistent with §§ 27.76(a)(3) (relating to exclusion and readmission of children and staff in child care group settings), 27.154(6) (relating to restrictions on caregivers in a child care group setting) and 27.155(6) (relating to restrictions on health care practitioners.

Thank you in advance for your consideration of the Academy's recommendations and concerns relating to important public policy and legal matters. If you have any questions, or would like to discuss any of the issues raised, please contact us at your convenience.

Sincerely,

Kevin P. Shaffer, M.D.
President

cc: PAFP Board of Directors
PAFP Public Policy Commission
Wanda D. Filer, M.D. – Chair, PAFP Public Policy Commission
John S. Jordan – PAFP Executive Vice President
Charles I. Artz, Esq. – PAFP General Counsel
Don McCoy, Pa. Medical Society

American Academy of Pediatrics

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Child Death Review Program
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Child Abuse Education Program
Cindy Christian, M.D.

July 3, 2000

James T. Rankin, Jr, DVM, MPH, PhD
Director, Division of Communicable Disease Epidemiology
PA Department of Health
P.O. Box 90
Harrisburg, PA 17108

Re: Proposed regulations on Reporting of Communicable and Non-communicable Diseases

Dear Dr. Rankin,

The PA Chapter of the American Academy of Pediatrics (PA AAP) supports the need for updated reporting regulations and offers the following comments to the proposed rulemaking on the reporting of communicable and non-communicable diseases in the Commonwealth.

1) Section 17.1 - Definitions. Caregiver and Child care group setting. These definitions are appropriately broad to encompass all types of group care in the Commonwealth, but they need to be adjusted to account for the practical limitations of checking vaccination status in settings where group care is transient and infrequent.

   Group care of young children increases their exposure and risk of communicable disease. By including all types of care where 4 or more children unrelated to the operator, the Department has properly addressed this risk. However, checking and reporting to the Department about aggregate status of vaccine records is not feasible in drop-in child care provided related to church services, court proceedings, in shopping malls and other temporary, transient child care settings. The best that could be accomplished in such settings is to require that parents who leave their children in such temporary care show evidence of their child's vaccination record. Even then, the personnel who work in such settings are unlikely to have the skills or time needed to determine from the record the parent might present whether the child is up to date for age.

   A reasonable modification would be to apply the regulations to all types of care where 4 or more children who are unrelated to the operator receive care for 10 or more hours in any week, or for 40 or more hours in any month.

2) Section 27.6 (c) - Disciplinary consequences for violating reporting responsibilities
The PA AAP is concerned with the regulations referral to consequences against a physician for failure to report. There is not sufficient detail in the proposed regulations to understand under what criteria disciplinary action would occur, whether there would be an appeal process and what actions would be taken against the physician. If the department wants to improve the rate of reporting, the goal should be to educate physician practices about the importance of reporting and to create a reporting process that is simple and accessible 24 hours per day/7 days per week.

3) Section 27.21a - Chickenpox/varicella
PA AAP supports making varicella a reportable disease but disagrees with the plan to obtain 3 years worth of reporting data from laboratories before requiring health care providers to report. We predict that the department will not get any data from laboratories since primary care practices rarely, if ever, lab test for VZV. School nurses and child care programs could report cases since often only the severest cases are seen by physicians.

4) Section 27.21a - Hepatitis
PA AAP supports reporting of all types of hepatitis.

5) Section 27.21c - Reporting of absentees
So that outbreaks among children in group care settings can be promptly investigated and managed, a similar requirement to that required under (c) for school nurse reporting of any unusual increase in the number of absentees among school children should be added for child care group settings that enroll more than 12 children – all child care center type programs, including nursery schools and Head Start center-based programs.

6) Section 27.30 - Reporting results of metabolic testing in the newborn child
PA AAP supports expanding the reporting to include all four of the conditions currently covered under the PA metabolic screening program. PA AAP recommends reporting of all metabolic diseases tested in the expanded NeoGen panel currently used by most PA birthing hospitals. It is in the epidemiological interest of the Commonwealth to monitor the frequency of these diseases for possible additions to the state metabolic screening program.

7) Section 27.34 - Lead Poisoning
PA AAP supports reporting of all childhood lead testing analyzed by clinical laboratories. Only by reporting the results of all childhood lead tests, regardless of the result, will the Commonwealth be able to determine an appropriate lead testing protocol for PA. PA AAP supports reporting via labs, since all venous and capillary lead testing is done through clinical laboratories.

8) Section 27.34(e) - Failure to report requested information to the clinical laboratory resulting in disciplinary consequences as specified in section 27.6 (c)
As indicated in the comment for section 27.6 (c), the PA AAP is concerned with the regulations referral to consequences against a physician for failure to report.

9) 27.71 - Exclusion of pupils and staff for specified diseases and infectious conditions
The section's wording is not consistent with the heading in addressing children and staff in schools and child care settings.

Old wording should be changed:
- from "pupils" to "children in child care and pupils in schools"
- from "school" to "child care group settings and schools"
- from "physician or the school nurse" to "physician, school nurse, or caregiver"

A physician or school nurse should not have to verify that the criteria for readmission have been satisfied unless there is a question on the part of the school or child care group setting. The criteria specified are very clear for most of the conditions. For example, physicians can do no more to ascertain the status of the child than a caregiver who would ask the parents about when the first crop of vesicles of chickenpox developed and look to see whether all the lesions have dried and crusted. Physicians and parents do not need to interact to confirm this status. Doing so would be a waste of time and resources.

The times when a health professional needs to be involved are clearly stated in the readmission criteria for conditions where such involvement is appropriate Where negative culture tests are required, such tests require involvement of a health professional as stipulated in the exclusion criteria. For lice, reexamination 7 days

post treatment for infestation by a health professional will be burdensome for parents and health professionals, but may reduce needless treatment with pesticides of children who may be thought to be infested when they have only empty egg casings or dandruff casts.

10) Section 27.72 - Exclusion of pupils and staff showing symptoms.
The PA AAP commends the Department for proposed wording in this section that is consistent with currently published national standards.

As in section 27.71, this section's wording is not consistent with the heading in addressing children and staff in schools and child care settings. Old wording should be changed:

- from "pupils" to "children in child care and pupils in schools"
- from "school" to "child care group settings and schools"
- from "physician or the school nurse" to "physician, school nurse, or caregiver"

11) Section 27.73 - Readmission of excluded pupils and staff
The first part of this section (a) should be deleted since the exclusion criteria that require health professional decision making are already included in the criteria for the specific conditions and symptoms.

In section (b), as in section 27.71, this section's wording is not consistent with the heading in addressing children and staff in schools and child care settings. Old wording should be changed:

- from "pupils" to "children in child care and pupils in schools"

12) Section 27.76 - Exclusion and readmission of children and staff in child care group settings
The reference to 27.71-27.75 will be unnecessary if the suggested inclusive wording changes are made.

Diarrhea should be deleted from the additional list of conditions that require physician verification for readmission. Physicians determine resolution of diarrhea, inability to prevent contamination of the environment with feces, and fever by asking the parent of the child, a task that caregivers can perform as well as physicians. The criteria for readmission should be retained in the regulation, but the requirement for physician verification should be deleted as

unnecessarily burdensome and costly. Item (iii) Identified bacterial or parasitic pathogen is too broad. Children and staff with the carrier state for Giardia lamblia do not need to be excluded from child care. Similarly, asymptomatic children and staff with salmonella other than *S typhi* in their stools do not need to be excluded. See p.253 and p.504 of the American Academy of Pediatrics, *Report of the Committee on Infectious Diseases, Red Book 2000*, 25th edition, 2000.

13) Section 27.77 - Immunization requirements for children in child care group settings

The PA AAP commends the Department for broadly including all children in child care settings in the requirement for documentation of vaccination as a condition of accepting or retaining a child 2 months of age or older in any child care setting.

This new regulation will effectively bring all facilities in the Commonwealth where child care takes place outside the current PA DPW regulatory authority under the same requirement for documentation of immunized status unless there is a religious or medical exception. In addition, this new regulation will give all the operators of child care group settings, including those regulated by PA DPW, the authority of the Department of Health to exclude children whose parents do not provide the documentation. Until now, the only sanction was the denial of license or issuance of a provisional license to DPW regulated facilities, with no requirement on the parent.

The PA AAP opposes the monitoring method proposed for documentation of vaccination status of children in child care group settings because it would impose a heavy administrative burden and require a level of expertise that cannot be met with the resources currently available to child care providers in group care settings. Few child care settings have health professionals to help with immunization record checks.

Section 27.77 Immunization requirements for children in child care group settings. *(a) Caregiver responsibilities* in the proposed new reporting system requires that caregivers not only collect certificates of immunization, but also periodically update the information, summarize it and report it on an annual basis to the Department of Health on a form provided by the Department. This requirement is similar to that required of schools, but child

care group settings do not have the resources available to schools to comply with such reporting and summarizing.

Among child care centers regulated by the PA Department of Welfare, few have any health personnel. In 1998, the PA American Academy of Pediatrics with resources provided under a contract with PA DPW, conducted a statewide telephone survey of a random, geographically representative sample of DPW-regulated child care centers and family child care homes. One of the areas explored in the survey was the use of health professional consultation by child care providers in the preceding 12 months. Only 29% of center directors and 11% of family child care providers reported seeking advice from any type of health professional and the majority of that advice was obtained without a fee. As economic pressures have increased in the health care system, such volunteer assistance from health professionals is ever more difficult to arrange.

Vaccination record review to determine up-to-date status of vaccines compared with a recommended schedule is a complex task that requires either the training and supervision by a health professional to review each record or the use of software that can apply the complex decision rules about which vaccines a child should have received at varying ages among children in child care settings. Unlike school entry when most of the vaccines should be complete and a single set of rules can be applied to the records, many children in child care are in the process of being immunized and must be tracked by age and over the period of enrollment as they become eligible for additional doses and types of vaccine. There are no school nurses to perform or to support this task in most child care group settings. The PA AAP has developed tools to assist child care providers in assessing up-to-date status of vaccination for enrolled children, such as the Immunization Dose Counter. With staff turnover rates of 31% to 40% per year and marginal staffing to carry out face-to-face ratios, few child care providers master the skills required for accurate checking of vaccination records.

The proposed regulations require a separate system that would duplicate, be less comprehensive and less current as a health promotion tool than the existing reporting system now in place for

child care centers and group homes regulated by the PA DPW, using DPW's Child Health Assessment Form, CY51.

The DPW CY51 form collects data on the up-to-date status and health problems for each child using the current nationally recommended routine preventive health services schedule. This schedule includes performance of screening for vision, hearing, anemia, growth, and lead, health history and physical examination findings as well as documentation of vaccinations. The CY51 form should not be duplicated or supplanted by any form or reporting requirements developed by DoH. Doing so would lessen the effectiveness of the more comprehensive system now in place described below.

PA childcare regulations 3270.131, 3280.131, and 3290.131 respectively for centers, group homes and family child care homes regulated by PA DPW, require that all child care providers must have documentation for each child that by no later than 60 days after enrollment, the child has received a health assessment and is completely immunized according to the current recommendations of the American Academy of Pediatrics. These recommendations are nationally recognized in both the private and public health sectors. They are the same as the current recommendations for vaccines of the ACIP and essentially the same as those for routine health supervision published in US Department of Health and Human Services, Bright Futures. A harmonized, updated schedule of current vaccine recommendations endorsed by ACIP, AAP and the Academy of Family Practice is published each January. Under §27.77 Immunization requirements for children in child care group settings (b) *Vaccination Requirements*, the proposed regulations reference the ACIP standards in effect on January 1,1999. These standards were superceded with a revised standard on January 1, 2000 and that standard will be superceded as new recommendations are made, each January. The existing PA DPW regulation references the current standard and therefore requires no revision as the national standard is updated each January.

Annually, PA DPW workers make licensing site visits and collect either a full set of the Child Health Assessment Form (DPW-CY51 form) or a 10% random sample of children enrolled in child care centers and group homes (but not

family child care homes) to assess regulatory compliance. The PA AAP is a contractor of both the PA DPW and the PA DoH. As defined in one of the contract deliverables in both contracts, ECELS receives all data collected by DPW on documentation of preventive care and immunization compliance reported on the Child Health Assessment Form (DPW-CY51) and analyzes the data with a proprietary software application (ECELSTRAK) developed by Stuart Weinberg, MD, FAAP. ECELSTRAK is a software application program that enables assessment of the timeliness of routine pediatric preventive care services and immunizations, generates administrative reports and program/parent reminders to enable child care programs and parents to maintain children in pediatric medical homes, and generates aggregate reports by zip code, county, region and statewide. Comparisons of accuracy of assessments made by child care providers and licensing regulatory staff without the use of ECELSTRAK and with the use of the software package affirm that assessments made by individuals without submission of the records for data processing by ECELSTRAK software are rarely accurate.

The ECELSTRAK system has not been applied to family child care homes because of limitations of resources for data processing. The current cost of drawing the sample, data processing, generation and prompt distribution of the individual center and aggregate reports by a DBE subcontractor is $6.89 per record checked. This system could and should be expanded to encompass the other child care group settings not now under surveillance: i.e. family child care homes, nursery schools regulated by the PA DoE, and other regulated and unregulated group care programs.

Contrary to the Department's statement in the proposed regulations, the PA DoH will require additional resources to check individual child vaccination records from child care group settings. Use of the CDC's CASA software or any other system requires data entry personnel. After data entry, summaries must not only be generated, but analyzed and returned to the child care providers so corrective action can be taken. Merely collecting data to report is insufficient unless the reports are tied to remedial action. ECELSTRAK reports back to the child care providers within a month of receipt of data from DPW. Aggregate reports are drawn

annually and provided to PA DoH. Undoubtedly, this on-site sampling and copying technique increases the error rates substantially. Currently, approximately 75% of the data entered into ECELSTRAK is drawn from vaccination and routine health service dates copied from a sample of records drawn on site by DPW representatives during their center licensing inspections. DPW recognizes the need to improve the accuracy of the data input and sampling. As the next step in the ongoing plan to build on nearly 10 years of work to develop the ECELSTRAK system, DPW intends to make submission of a full set of CY51 forms for all enrolled children a mandatory part of the center licensing process. Preparation of the child care provider community and the DPW licensing staff for this next step has been underway for several years. Interfering with this careful groundwork and already operational system would be both wasteful and regressive.

Alternately, DoH and DPW could collaboratively work to develop, support and internalize existing systems of medical record checking that includes all recommended preventive health services (vaccinations and screening tests) as is now done by ECELSTRAK.

14) Section 27.154 - Restrictions on caregivers in a child care group setting

Diarrhea should be deleted from the list of conditions that require physician verification for readmission. Physicians determine resolution of diarrhea in an adult by asking the patient if the diarrhea symptoms have subsided, a task that the operator of a child care group setting can perform as well as physicians. The criteria for readmission should be retained in the regulation, but the requirement for physician verification should be deleted as unnecessarily burdensome and costly.

15) PA AAP proposes that the department consider making immunization delivery a reportable event, as the Philadelphia Department of Public Health did several years ago, to allow for future implementation of the statewide immunization information system (registry). The language should permit reporting by all health care providers and/or insurers which is free of liability for any violation of medical record privacy/confidentiality.

Thank you for the opportunity to respond to this proposed rulemaking. If you have any questions regarding these comments please contact Suzanne Yunghans, PA AAP Executive Director, at (610) 520-9123. For questions about the comments related to regulation of child care group settings, please contact Susan Aronson, MD, FAAP at (610) 664-3923.

Sincerely.

Mark Reuben/sy

Mark S. Reuben, MD
President

Original: 2119

PHCCPA
PA Home-based Child Care Providers Association
23 N. Scott Avenue ~ Glenolden, PA 19036
Phone (610)583-0964 ~ Fax (610)461-4812 ~ Email francyne@earthlink.net

June 29, 2000

To: The Pennsylvania Department of Health

PROPOSED REGULATIONS CONCERNING CHILD CARE HOMES

It has come to our attention that the Department of Health has set forth proposed rulemaking which will effect any home-based provider caring for four or more children. The PHCCPA has developed meaningful relationships with Department of Health nurses and other staff. Our association values the knowledge of those staff and uses them to present health information at our training and conferences. However, it is the Department of Public Welfare that we look to for regulation that guides our businesses in all areas, including health. It is assumed by this association that the Department of Public Welfare is the governing agency in development, implementation and enforcement of regulation. The PHCCPA welcomes information from the Department of Health in an effort to improve the quality of care for children in child care homes. The PHCCPA maintains an ongoing relationship with the American Academy of Pediatrics, Pennsylvania Chapter and its Early Childhood Education Linkage System (ECELS) as to stay informed of health matters relating to children and caregivers. Information in *30 Pa.B. 2715* appears to conflict with the standards that we are now following as home-based providers in the area of procedures involving such matters as communicable diseases. The intent of this letter is to make the Department of Health aware of the confusion that will be caused to providers both in content and representation surrounding the proposal to amend *Chapter 27*.

Sincerely,

Francyne Wharton

Francyne Wharton
PHCCPA, Director

"Sharing the Caring Across Pennsylvania"

FAX COVER SHEET

Francyne Wharton
23 N. Scott Avenue

Glenolden, PA 19036

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SEND TO	
Company name: Dept. of Heath	From: Francyne Wharton
Attention: Paula Combs	Date: 6/29/00
Office location:	Office location: PHCCCA
Fax number: (717) 722-6975	Phone number: (610) 583-0964

☐ Urgent ☐ Reply ASAP ☐ Please comment ☐ Please review ☑ For your information

Total pages, including cover: 2

COMMENTS

Paula
(717) 705-6042

Sam

Commonwealth of Pennsylvania

Department of Health

HARRISBURG

Original: 2119 June 29, 2000

Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
14th Floor, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Department of Health Proposed Regulation No. 10-156
Communicable and Noncommunicable Diseases

Dear Mr. Nyce:

The Pennsylvania Department of Health has recently received the enclosed public comments to the above-referenced regulations.

Sincerely,

Yvette M. Kostelac
(LF)

Yvette M. Kostelac
Assistant Counsel

Enclosure

cc: James T. Rankin, Jr.
Joel H. Hersh

Quest Diagnostics Incorporated

900 Business Center Drive
Horsham, PA 19044
215.957.9300

Original: 2119

June 26, 2000

James T. Rankin, Jr., D.V.M., M.P.H., Ph.D.
Director, Division of Communicable Disease Epidemiology
Department of Health
P.O. Box 90
Harrisburg, PA 17108

Dear Dr. Rankin:

Quest Diagnostics Incorporated, based in Teterboro, New Jersey, is the nation's leading provider of diagnostic testing, information and services to physicians, hospitals, managed care organizations, employers and government agencies with regional laboratories in Pittsburgh, West Norriton and Horsham, Pennsylvania. The wide variety of tests performed on human tissue and body fluids help physicians to diagnose, treat and monitor patients.

Quest Diagnostics appreciates the opportunity to comment on the proposed amendments to Chapter 27 relating to communicable and noncommunicable diseases. Attached is a list of our specific concerns about individual sections of the regulations. In the attached list, we have underlined our proposed new language and marked as delete or crossed out language we propose be deleted. In italics, below each section, we explain the reasons for our proposed changes. Electronic reporting to various locations produces an additional burden on laboratories. Reporting to a central location which can then forward information to the appropriate agency is more efficient and avoids redundancy.

Please feel free to contact me regarding any of our comments. We are confident that our proposed changes will meet with your support and approval and would be happy to discuss them with you in more detail.

Sincerely yours,

Herman Hurwitz, M.D., F.C.A.P.
Medical Director Mid Atlantic Region

cc: Robert E. Nyce, Executive Director, Independent Regulatory Review Commission
The Honorable Harold F. Mowery, Jr., Chair, Senate Public Health and Welfare Committee
The Honorable Dennis M. O'Brien, Chair, House Health and Human Services Committee

Attachments

~~Strikethrough~~ = Deletion
Bold underlined = Insertion

Pennsylvania Department of Health
28 PA. Code Chapter 27
Comments to Proposed Rulemaking

Section 2.4(b) Delete (2)-(7)

Clinical laboratories that are reporting electronically should be sending all reports, except cancer, to a central location. The file can be separated to specific Divisions and appropriate health authorities once received by the Department.

Section 27.6(a) Failure of a clinical laboratory to comply with the reporting provisions of this chapter, **unless due to circumstances beyond the control of the clinical laboratory,** may result in restrictions being placed upon or revocation of the laboratory's permit to operate as a clinical laboratory, as provided for in the Clinical Laboratory Act (35 P.S. 1251-2165).

Example: To comply with the reporting provisions of this chapter the clinical laboratory has to rely on information provided by the person who orders testing. Information not provided when solicited will result in a failure to comply with this chapter.

Section 27.21(a)(1) Add **All Blood Lead test results on pregnant women**

The clinical laboratory does not have a means to determine if the patient is pregnant. Because of such limitation the health care practitioner and health care facility shall have the duty to report such cases.

Section 27.22(a) Add **While normally the laboratory that performs the examination should report, in the case of lab-to-lab referrals, either the referring or the performing laboratory may report.**

To ensure that the Department receives a report which contains the most complete information and to eliminate unnecessary duplicate reporting, the referring and performing laboratories shall formally agree which laboratory is responsible to provide the report. The referral laboratory that is performing the examination may not be provided with all the demographic information required to make a complete report to the Department.

Section 27.22(c) Reports shall be made to the appropriate health authority of the county or municipal department of health if it can be determined that the patient resides in one of those cities or counties. Other reports shall be submitted to the Division of Communicable Disease Epidemiology, Bureau of Epidemiology. Report of ~~maple syrup urine disease, phenylketonuria, primary congenital hypothyroidism, sickle cell hemoglobinopathies,~~ cancer, ~~sexually transmitted diseases and lead poisoning~~ shall be reported to the location specifically designated in this subchapter. ~~See 27.30, 27.31, 27.33 and 27.34.~~

~~Strikethrough~~ = Deletion
Bold underlined = Insertion

Clinical laboratories that are reporting electronically should be sending all reports, except cancer, to a central location. The file can be separated to specific Divisions and appropriate health authorities once received by the Department.

Section 27.22(f) A clinical laboratory **that cannot perform serotyping** shall submit isolates of salmonella and shigella to the Department's Bureau of Laboratories for serotyping within 5 work days of isolation.

Laboratories that have the capability to perform serotyping can report to the Department the results of such testing eliminating the necessity to mail a biohazardous specimen to the Department's Bureau of Laboratories.

Section 27.22(g) A clinical laboratory **that cannot perform serogrouping** shall submit isolates of Neisseria meningitidis obtained from a normally sterile site to the Department's Bureau of Laboratories for serogrouping within 5 work days of isolation.

Laboratories that have the capability to perform serogrouping can report to the Department the results of such testing eliminating the necessity to mail a biohazardous specimen to the Department's Bureau of Laboratories.

Section 27.22(h) A clinical laboratory **that cannot perform toxin typing;** shall send isolates of enterohemorrhagic E. coli to the Department's Bureau of Laboratories for appropriate further testing with 5 work days of isolation.

Laboratories that have the capability to perform toxin typing can report to the Department the results of such testing eliminating the necessity to mail a biohazardous specimen to the Department's Bureau of Laboratories.

Section 27.22(i) A clinical laboratory **that cannot perform serotyping** shall send isolates of Haemophilus influenzae obtained from a normally sterile site to the Department's Bureau of Laboratories for serotyping within 5 work days of isolation.

Laboratories that have the capability to perform serotyping can report to the Department the results of such testing eliminating the necessity to mail a biohazardous specimen to the Department's Bureau of Laboratories.

Section 27.22(k) Delete

Clinical laboratories that are reporting electronically should be sending all reports, except cancer, to a central location. The file can be separated to specific Department's of Health once received by the Department.

Section 27.30 Delete

~~Strikethrough~~ = Deletion
Bold underlined = Insertion

Clinical laboratories that are reporting electronically should be sending all reports, except cancer, to a central location. The file can be separated to specific Divisions and appropriate health authorities once received by the Department.

Section 27.34(a) A clinical laboratory shall report all blood lead test results on both venous and capillary specimens for persons under 16 years of age ~~and pregnant women~~ to the Childhood Lead Poisoning Prevention Program, Division of Maternal and Child Health, Bureau of Family Health.

The clinical laboratory does not have a means to determine if the patient is pregnant. Because of such limitation the health care practitioner and health care facility shall have the duty to report such cases.

Section 27.34(h) Delete

The laboratory has a responsibility to provide to the person ordering the testing a form that solicits the information which is required for completion of the applicable case report. (Section 27.7(1). The person who orders testing has a responsibility to provide the laboratory with the information. (Section 27.7(2). As the regulations are clear in disciplinary consequences and criminal penalties for violations the laboratories should not be required to follow an additional burdensome process.

Section 27.96 Delete

A separate Section for sexually transmitted diseases is not required. Diagnostic tests for all diseases should be performed following a standard or approved test procedure, including the use of FDA approved tests where applicable.
Note: The Food and Drug Administration approves test kits, not tests.

Section 27.97 A person under the age of 21 may give consent for medical and other health services **including venipuncture and clinical laboratory testing** to determine the presence of or to treat a sexually transmitted disease and any other reportable disease, infection or condition. If the minor consents to undergo diagnosis or treatment, approval or consent of another person is not necessary. The physician **and clinical laboratory if any** may not be sued or held liable for **venipuncture and testing services,** implementing appropriate diagnostic measures or administering appropriate treatment to the minor if the minor has consented to the procedures or treatment.

Additional language to protect clinical laboratories for the services they provide in such a circumstance.

~~Strikethrough~~ = Deletion
Bold underlined = Insertion

PENNSYLVANIA CATHOLIC CONFERENCE

223 North Street • Box 2835 • Harrisburg, PA 17105 • (717) 238-9613 • FAX (717) 238-1473

Original: 2119

June 27, 2000

VIA FAX AND FIRST CLASS MAIL

James T. Rankin, Jr., D.V.M., M.P.H., Ph.D.
Director
Division of Communicable Disease Epidemiology
Department of Health
P.O. Box 90
Harrisburg, PA 17108

Re: Proposed Rule Making Regarding Reporting of Communicable and Noncommunicable Diseases

Dear Dr. Rankin:

Please find enclosed a memorandum I received from the legal counsel of the Pennsylvania Catholic Conference analyzing the above referenced proposed regulation. As you can see from the memorandum, the Pennsylvania Catholic Conference has serious concerns with regard to these proposed regulations. It may very well be possible that we are misunderstanding these regulations. Nonetheless, since we have more than 220,000 students in Catholic schools and a large population of children in childcare centers, we believe it would be beneficial to both the Department of Health and the Pennsylvania Catholic Conference to have a discussion regarding these regulations.

As it stands now, we are opposed to these regulations based on the concerns set forth in the accompanying memorandum. I look forward to discussing this issue with someone from the Department of Health.

Very truly yours,

Fredrick Cabell, Jr., Esq.
Director, Education Department

FC/clv
Enclosure
cc: The Independent Regulatory Review Commission
The Honorable Dennis M. O'Brien
The Honorable Harold F. Mowery, Jr.

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VIA FAX

June 27, 2000

Original: 2119

MEMORANDUM TO: Fredrick Cabell, Jr., Esq.
Director, Education Department
Pennsylvania Catholic Conference

RE: Reports of Communicable and Noncommunicable Diseases

The Department of Health has issued proposed rules for comment regarding reports of communicable and noncommuniable diseases. It should be noted that these proposed regulations now apply to child care group settings ("CCGS") (defined as any premises in which care is provided to four or more children). In addition, they appear to expand upon the reporting and screening duties previously required of schools, including parochial schools.

The *Pennsylvania Bulletin* states that comments are due within 30 days. Given the need to respond immediately, we will not be able to provide you with a detailed analysis at this time. However, we have the following observations.

1. In general, the duties imposed upon child care providers appear to be greater than those placed upon school officials. In each case, however, the potential for significant burdens arises—both with respect to school, and child care provider compliance and with respect to parental responsibilities and expenses.

2. As noted above, both schools and child care providers appear to be affected by the proposed regulations. However, there is no separate definition for "schools" or "child care providers." Instead, there is a single

definition for a "child care group setting." That term is defined as any "premises in which care is provided at any one time to four or more children unrelated to the operator." Schools certainly provide care to four or more children and would seem to be a subset of "child care group settings." This interpretation is supported by the fact that §27.77 is entitled "Immunization requirements for children in *child care group settings*" and subsection (d) of §27.77 excludes kindergarten, elementary and higher schools from its application. This suggests that, absent the exemption in subsection (d), schools would fall within the scope of "child care group settings."

3. Pursuant to §27.23, individuals in charge of child care group settings "shall have the same reporting responsibilities as health care practitioners have under §27.21a." Section 27.21a(b) provides that a health care practitioner ("HCP") is required to report a case if the HCP "*treats* or *examines*" a person suffering from or suspected of having a reportable disease, infection or condition.

Individuals in charge of child care group settings, unlike health care practitioners, typically do not "*treat or examine*" persons with communicable diseases. Thus, the precise nature and scope of their duties under this section is unclear. Are schools and child care providers to become mini health clinics pursuant to these regulations?

4. Section 27.71 appears to require that a child cannot be readmitted to school, unless the school nurse or a physician has verified that the criteria for readmission have been met. (§27.76 seems to require a physician verification in all instances.) Many parochial schools do not have full time school nurses. Also, a number of the listed diseases have specific time-frames for readmission set forth. If the time-frame is satisfied, is it necessary to incur the expense of an additional doctor's visit? Would verification by a nurse or physician's assistant be satisfactory, less expensive, and more easily obtained?

5. Section 27.72 also requires that a child be excluded if he has a fever or is vomiting and the school is to maintain a record of the exclusion. Under §27.73, a child excluded for these reasons cannot be readmitted unless the school nurse or a physician is satisfied that the condition is not communicable. This would seem to require that children be seen by a school nurse or physician whenever they have an upset stomach before they can be readmitted to school.

6. Section 27.76(b) provides that "the caregiver at a child care group setting *shall* arrange for the following:

(3) Screening of each child by staff at the time the child is brought to the child care group setting for the presence of a condition which requires exclusion. The screening shall be conducted each day while the parent . . . is present.

On its face, this provision requires that every child who is brought to a child care provider (and, perhaps, school) be screened every day for the presence of a condition that requires exclusion. This would include screening for the 15 diseases specified in §27.71, and the additional conditions set forth in §§27.72 and 27.76 (including fever). Surely such a requirement is unreasonable, unduly burdensome and exceedingly costly; not to mention time consuming. Every child would need to be subjected to a daily medical exam before being allowed in care or school. How would it be administered?

7. Finally, it should be noted that §27.8 provides for criminal penalties for violation of any of these provisions. This includes the potential for fines and imprisonment.

BALL, MURREN & CONNELL

BY: Maura K. Quinlan

Maura K. Quinlan

MKQ/nll

cc: Dr. Robert J. O'Hara, Jr.

Yvette Kostelac

Original: 2119

KEYSTONE CHRISTIAN EDUCATION ASSOCIATION
6101 Bell Road
Harrisburg, Pennsylvania 17111

FAX COVER SHEET

DATE:	6/27/00	**TIME:**	5:10 PM
TO:	Dr. James T. Rankin Director, Communicable Disease Epidemiology	**PHONE:** **FAX:**	717 787-3350 717 772-6975
FROM:	Terry C Bachur KCEA	**PHONE:** **FAX:**	(717) 564-1164 (717) 564-1163

Number of pages including cover sheet: 1

Message

Dear Dr. Rankin,

As I mentioned in my phone call, we just became aware of the proposed changes in the Chapter 27 regulations. We then had some difficulty contacting you because the phone number listed in the notice in the Pennsylvania Bulletin was a non-working number. As I mentioned, I will briefly outline a few of our concerns and will follow up with a more detailed letter explaining our concerns. In light of the difficulties in reaching you, and because of the seriousness of the ramifications of our concerns, we would request an extension of the comment period for a week so we and your Department can assess the need for further dialog regarding some aspects of these proposed regulations.

We note references to a "school nurse" to perform certain functions. There are basically no School Nurses functioning within the ranks in many of the Non-Public, Non-Licensed schools. What implications are there under these regulations if no other entity is designated to perform these functions?

We have serious concerns about the requirement regarding determining and reporting "unusual rates" of absenteeism. The proposed periodic publishing of the "unusual rates" in the Pennsylvania Bulletin leaves our schools with no practical way to keep abreast of your prevailing standards.

A number of concerns arise out of the requirements placed on staff and management of those involved in "child care group setting." How could an individual in charge of a "child care setting" be able to accurately diagnose and "screen children for exclusion?" Furthermore, how are "care givers" to screen children each day as they are brought to the child care group setting, for the presence of conditions requiring exclusion? How can child care staff be expected to diagnose and report to the Department at the same level as a "health care facility?"

We would appreciate the opportunity to review these proposed regulations with you to ensure that these regulations will be practical and effective for all that will be covered by them.

Sincerely

Terry C Bachur

Original: 2119

June 27, 2000

James T. Rankin Jr., D.V.M., M.P.H., Ph.D., Director
Division of Communicable Disease Epidemiology
Pennsylvania Department of Health
2635 Paxton Street
Harrisburg, Pennsylvania 17108

Dear Sir:

The Pennsylvania Health Care Association (PHCA) is a professional trade organization of more than 600 members representing all aspects of the long term care spectrum, from home health and adult day care to assisted living residences and sub-acute care.

In satisfying our responsibility to provide proactive representation on policy making issues affecting our members we herein submit the following comments to the proposed rulemaking for the reporting of communicable and non-communicable diseases published in the *Pennsylvania Bulletin* on May 27, 2000.

Please note that we have restricted our comments to those sections of the proposed rule affecting the long term care environment and welcome any communication to clarify our intent.

General Comments

- Are the "routine" infections in long term care of MRSA and VRE excluded from the provisions of this rule; specifically, the outbreak reporting and isolation requirements?
- If these diseases are to be included would this rule supersede 28 PA Code chapter 211, section 1, Reportable Diseases, of the licensure regulations for long term care nursing facilities?

Specific Comments by Section

1. Section 27.4 Reporting Cases:

   Will the Department provide health care facilities and practitioners with a list of address or phone number changes if there is a move of the location to which "diseases and conditions are to be reported"?

2. Section 27.6 Disciplinary consequences for violating reporting responsibilities.

   Exactly who is responsible for reporting what?
   Who is responsible to report first, second, ect.? For example, will there be an expected order, such as the laboratory, which often is the first to identify specific organisms in specimen?
   If one report is filed are other health care practitioners still responsible to report?

Will there be any obligations imposed on the reporting practitioners to communicate to other involved health care practitioners that (1) a report has been filed with the Department, and (2) to report the findings in a timely manner to other practitioners that need to know.

3. Section 27.7 Cooperation between clinical laboratories and persons who order laboratory tests.

   Clarification is needed as to who the "individual requesting the test" refers. In LTC a test may be ordered by the physician, however, it is the nurse who usually completes the test requisition.
   Also, if laboratories are to provide the appropriate laboratory requisition slips who is responsible to obtain these? Will labs be responsible to distribute to those facilities with which it contracts? Some of the difficulties that LTC faces are distinct from those of hospitals, which may have internal laboratories. LTC contracts for these services, has no control over the laboratory, frequently gets results that are delayed in reporting and other real and potential problems in communication. Therefore, regulations should take into account these complicated contractual arrangements.

4. Section 27.8 Criminal penalties for violating the act or this chapter.

   Apparently the Department believes that there is/has been considerable lack of compliance to justify criminal penalties being imposed. The Department has a responsibility therefore to be *very specific* on the requirements, (who must do what and in what time periods and how, etc.), with which failure to comply will result in criminal penalties.

5. Section 27.9 Authorized departures from the regulations.

   How does the Department plan to communicate in a timely manner about these exceptions within a 90 day expiration time?

6. Chickenpox (varicella)

   "It is not yet clear that chickenpox can be prevented by a new vaccine." This comment is outdated. Varicella vaccine is now recommended universally for children and others who are known not to be immune. Also, if chickenpox reporting is determined to be regulated and required does the Department distinguish between the occurrence of the disease, and post-vaccination cases?

7. Section 27.25

   Although this section is being "reserved" because the Department "proposes to delete this section, which pertains to reports by health care practitioners who are not physicians, as the requirement that other licensed health care practitioners

report cases is included in proposed §27.21a." We were unable to find definitive information in 27.21a that clarifies whom is responsible to report; please clarify.

Subchapter C. Quarantine and Isolation General Provisions

8. Section 27.60 Disease control measures

There is considerable controversy over the appropriateness and need for isolation of some infections. There are many reports and research in the literature declaring differing approaches to isolation in health care facilities. We are concerned that LTC may find itself in direct conflict with regulations and therefore would be literally forced to accept the Department's interpretation of whether or not isolation was indicated and even what type and how much.

Specifically, our concern is with the unmentioned yet often seen infections of VRE, MRSA. May we assume that the "isolation" in the proposal does not apply since neither infection is mentioned? Also, a facility may isolate a patient with Salmonella, but not always with the practice of universal Standard Precautions.

"This proposed section is important to the Department's disease control and prevention function, in that in would allow the Department the discretion to implement the most appropriate disease control measures for the situation."

While we recognize the need to coordinate the varying lines of authority in any organization this statement gives all authority to the Department to determine isolation requirements without any recognition of a facility's systems. The LTC industry is currently burden with the Department imposed two-step tuberculin skin testing for new employees that neither the CDC nor OSHA requires. Thus, we lack confidence that this same Department would be either reasonable or in concert with current recommendations and medical science in exercising any further "discretionary" measures. Some measure of recognition must be given in this section for a health care facility's existing, and regulatory required, infection control systems to prevent the future imposition of arbitrary and capricious measures.

Definitions

9. "Communicable disease—An illness **[due to an infectious agent or its toxic products which is transmitted, directly or indirectly, to a susceptible host from] which is capable of being spread to a susceptible host through the direct or indirect transmission of an infectious agent or its toxic product by** an infected person, animal or anthropod, **[or through the agency of an intermediate host, or a vector]** or through the inanimate environment."

This broad definition takes in any and all infectious diseases including such as MRSA, VRE. Since these are not listed in the proposed regulation does that imply they are not to be "regulated?" Further, if they are to be excluded from the purview of the Department are facilities free to determine their own procedures for isolation, infection control, etc.?

10. **"Health care practitioner—An individual who is authorized to practice some component of the healing arts by a license, permit, certificate, or registration issued by a Commonwealth licensing agency or board."**

Does this broad definition therefore require CNAs to report communicable diseases?

11. "Isolation—This separation for the **[period of communicability] communicable period** of **an** infected **[persons] person** or **[animals] animal** from other persons or animals, in **[places and under conditions that prevents] such a manner as to prevent** the direct or indirect transmission of the infectious agent from infected persons or animals to other persons who are susceptible or who may spread the disease to others."

Please clarify if "separation" is to be interpreted by surveyors to require any patient/resident with any infection to be "isolated." We are concerned with the latitude for interpretation on all sides.

12. **(b.) A person required to report under this chapter who suspects a public health emergency, shall report an unusual occurrence of a disease, infection, or condition not listed as reportable in Subchapter B (relating to reporting of diseases, infections and conditions) or defined as an outbreak, within 24 hours, and in accordance with the requirements of §27.4.**

Is reporting required when suspected or not until confirmed, microbiological or based on other tests such as smear results? Please provide specific instructions.

Quest Diagnostics Incorporated

900 Business Center Drive
Horsham, PA 19044
215.957.9300

Original; 2119

June 26, 2000

James T. Rankin, Jr., D.V.M., M.P.H., Ph.D.
Director, Division of Communicable Disease Epidemiology
Department of Health
P.O. Box 90
Harrisburg, PA 17108

Dear Dr. Rankin:

Quest Diagnostics Incorporated, based in Teterboro, New Jersey, is the nation's leading provider of diagnostic testing, information and services to physicians, hospitals, managed care organizations, employers and government agencies with regional laboratories in Pittsburgh, West Norriton and Horsham, Pennsylvania. The wide variety of tests performed on human tissue and body fluids help physicians to diagnose, treat and monitor patients.

Quest Diagnostics appreciates the opportunity to comment on the proposed amendments to Chapter 27 relating to communicable and noncommunicable diseases. Attached is a list of our specific concerns about individual sections of the regulations. In the attached list, we have underlined our proposed new language and marked as delete or crossed out language we propose be deleted. In italics, below each section, we explain the reasons for our proposed changes. Electronic reporting to various locations produces an additional burden on laboratories. Reporting to a central location which can then forward information to the appropriate agency is more efficient and avoids redundancy.

Please feel free to contact me regarding any of our comments. We are confident that our proposed changes will meet with your support and approval and would be happy to discuss them with you in more detail.

Sincerely yours,

Herman Hurwitz

Herman Hurwitz, M.D., F.C.A.P.
Medical Director Mid Atlantic Region

cc: Robert E. Nyce, Executive Director, Independent Regulatory Review Commission
The Honorable Harold F. Mowery, Jr., Chair, Senate Public Health and Welfare Committee
The Honorable Dennis M. O'Brien, Chair, House Health and Human Services Committee

Attachments

~~Strikethrough~~ = Deletion
Bold underlined = Insertion

Pennsylvania Department of Health
28 PA. Code Chapter 27
Comments to Proposed Rulemaking

Section 2.4(b) Delete (2)-(7)

Clinical laboratories that are reporting electronically should be sending all reports, except cancer, to a central location. The file can be separated to specific Divisions and appropriate health authorities once received by the Department.

Section 27.6(a) Failure of a clinical laboratory to comply with the reporting provisions of this chapter**, unless due to circumstances beyond the control of the clinical laboratory,** may result in restrictions being placed upon or revocation of the laboratory's permit to operate as a clinical laboratory, as provided for in the Clinical Laboratory Act (35 P.S. 1251-2165).

Example: To comply with the reporting provisions of this chapter the clinical laboratory has to rely on information provided by the person who orders testing. Information not provided when solicited will result in a failure to comply with this chapter.

Section 27.21(a)(1) Add **All Blood Lead test results on pregnant women**

The clinical laboratory does not have a means to determine if the patient is pregnant. Because of such limitation the health care practitioner and health care facility shall have the duty to report such cases.

Section 27.22(a) Add **While normally the laboratory that performs the examination should report, in the case of lab-to-lab referrals, either the referring or the performing laboratory may report.**

To ensure that the Department receives a report which contains the most complete information and to eliminate unnecessary duplicate reporting, the referring and performing laboratories shall formally agree which laboratory is responsible to provide the report. The referral laboratory that is performing the examination may not be provided with all the demographic information required to make a complete report to the Department.

Section 27.22(e) Reports shall be made to the appropriate health authority of the county or municipal department of health if it can be determined that the patient resides in one of those cities or counties. Other reports shall be submitted to the Division of Communicable Disease Epidemiology, Bureau of Epidemiology. Report of ~~maple syrup urine disease, phenylketonuria, primary congenital hypothyroidism, sickle cell hemoglobinopathies,~~ cancer, ~~sexually transmitted diseases and lead poisoning~~ shall be reported to the location specifically designated in this subchapter. See ~~27.30,~~ 27.31, ~~27.33 and 27.34.~~

~~Strikethrough~~ = Deletion
Bold underlined = Insertion

Clinical laboratories that are reporting electronically should be sending all reports, except cancer, to a central location. The file can be separated to specific Divisions and appropriate health authorities once received by the Department.

Section 27.22(f) A clinical laboratory **that cannot perform serotyping** shall submit isolates of salmonella and shigella to the Department's Bureau of Laboratories for serotyping within 5 work days of isolation.

Laboratories that have the capability to perform serotyping can report to the Department the results of such testing eliminating the necessity to mail a biohazardous specimen to the Department's Bureau of Laboratories.

Section 27.22(g) A clinical laboratory **that cannot perform serogrouping** shall submit isolates of Neisseria meningitidis obtained from a normally sterile site to the Department's Bureau of Laboratories for serogrouping within 5 work days of isolation.

Laboratories that have the capability to perform serogrouping can report to the Department the results of such testing eliminating the necessity to mail a biohazardous specimen to the Department's Bureau of Laboratories.

Section 27.22(h) A clinical laboratory **that cannot perform toxin typing** shall send isolates of enterohemorrhagic E. coli to the Department's Bureau of Laboratories for appropriate further testing with 5 work days of isolation.

Laboratories that have the capability to perform toxin typing can report to the Department the results of such testing eliminating the necessity to mail a biohazardous specimen to the Department's Bureau of Laboratories.

Section 27.22(i) A clinical laboratory **that cannot perform serotyping** shall send isolates of Haemophilus influenzae obtained from a normally sterile site to the Department's Bureau of Laboratories for serotyping within 5 work days of isolation.

Laboratories that have the capability to perform serotyping can report to the Department the results of such testing eliminating the necessity to mail a biohazardous specimen to the Department's Bureau of Laboratories.

Section 27.22(k) Delete

Clinical laboratories that are reporting electronically should be sending all reports, except cancer, to a central location. The file can be separated to specific Department's of Health once received by the Department.

Section 27.30 Delete

~~Strikethrough~~ = Deletion
Bold underlined = Insertion

Clinical laboratories that are reporting electronically should be sending all reports, except cancer, to a central location. The file can be separated to specific Divisions and appropriate health authorities once received by the Department.

Section 27.34(a) A clinical laboratory shall report all blood lead test results on both venous and capillary specimens for persons under 16 years of age ~~and pregnant women~~ to the Childhood Lead Poisoning Prevention Program, Division of Maternal and Child Health, Bureau of Family Health.

The clinical laboratory does not have a means to determine if the patient is pregnant. Because of such limitation the health care practitioner and health care facility shall have the duty to report such cases.

Section 27.34(h) Delete

The laboratory has a responsibility to provide to the person ordering the testing a form that solicits the information which is required for completion of the applicable case report. (Section 27.7(1). The person who orders testing has a responsibility to provide the laboratory with the information. (Section 27.7(2). As the regulations are clear in disciplinary consequences and criminal penalties for violations the laboratories should not be required to follow an additional burdensome process.

Section 27.96 Delete

A separate Section for sexually transmitted diseases is not required. Diagnostic tests for all diseases should be performed following a standard or approved test procedure, including the use of FDA approved tests where applicable.
Note: The Food and Drug Administration approves test kits, not tests.

Section 27.97 A person under the age of 21 may give consent for medical and other health services **including venipuncture and clinical laboratory testing** to determine the presence of or to treat a sexually transmitted disease and any other reportable disease, infection or condition. If the minor consents to undergo diagnosis or treatment, approval or consent of another person is not necessary. The physician **and clinical laboratory if any** may not be sued or held liable for **venipuncture and testing services,** implementing appropriate diagnostic measures or administering appropriate treatment to the minor if the minor has consented to the procedures or treatment.

Additional language to protect clinical laboratories for the services they provide in such a circumstance.

~~Strikethrough~~ = Deletion
Bold underlined = Insertion

Original: 2119

PENNSYLVANIA
SCHOOL BOARDS
ASSOCIATION, INC.

774 LIMEKILN ROAD, NEW CUMBERLAND, PA 17070-2398 / (717) 774-2331 / FAX (717) 774-0718

June 26, 2000

Robert E. Nyce, Executive Director
Independent Regulatory Review Commission
Commonwealth of Pennsylvania
333 Market Street
14th Floor
Harrisburg, PA 17101

Dear Mr. Nyce,

Enclosed are the comments of the Pennsylvania School Boards Association to the Department of Health concerning proposed revisions to Title 28, Part II, Chapter 27, on communicable and noncommunicable diseases, that was published in the May 27, 2000 issue of the *Pennsylvania Bulletin*. Our comments focus on changes that will affect children and staff in school settings.

Generally, we are supportive of the proposal that extends the requirements under the existing regulation to school staff as well as students. However, we believe that there are a few issues within the proposal that need to be clarified. We recommend that the department establish a definition of "school employee" that would clearly state what personnel must comply with the provisions, as well as indicate who does not have to comply. We also suggest that volunteers in schools be specifically excluded from the requirements and that language, if so necessary, simply state that school officials have the authority to prohibit volunteers from working with students and employees if it is believed that a health risk exists.

We also suggest that the proposal clearly state that a school nurse *or* physician is equally able to determine if an employee or student may be readmitted to school. Most schools do not have a nurse in the building every day; in addition, the function of school nurses is to focus on the health of students, not employees, on a routine basis. Finally, we urge the department to clarify new recordkeeping duties for schools and develop guidelines and forms to assist them with this task.

We offer these comments to you as the proposal moves through the regulatory review process. Please contact me if you have any questions regarding the issues addressed in this letter.

Sincerely,

Thomas J. Gentzel
Assistant Executive Director
Governmental and Member Relations

PENNSYLVANIA
SCHOOL BOARDS
ASSOCIATION, INC.

774 LIMEKILN ROAD, NEW CUMBERLAND, PA 17070-2398 / (717) 774-2331 / FAX (717) 774-0718

June 26, 2000

James T. Rankin, Jr., Director
Division of Communicable Disease Epidemiology
Department of Health
P.O. Box 90
Harrisburg, PA 17108

Dear Dr. Rankin:

The Pennsylvania School Boards Association would like to take this opportunity to provide comments concerning the department's proposed revisions to Title 28, Part II, Chapter 27 regarding communicable and noncommunicable diseases, that was published in the May 27, 2000 issue of the *Pennsylvania Bulletin*. Our comments will focus on changes to sections 27.71 through 27.75 that affect children and staff in school settings.

Generally, we are supportive of the proposal that extends the requirements under the existing regulation to school staff as well as students. We agree with the department's reasoning that attempts to prevent and control the spread of disease would be more effective if both students and staff having or suspected of having a communicable disease were excluded from school. However, we believe that there are issues and specific language within the proposal that need to be clarified.

First, in order to abate any confusion that may occur in the interpretation of the regulations, we recommend that the department clearly define what adults are affected by the provisions. Section 27.71 refers to "a staff person who has contact with pupils." Does that mean only teachers and administrators, or does it include custodians, cafeteria workers and bus drivers? Does it include contractors or employees of contractors? What does "contact with pupils" mean; that is, what kind of contact and/or how frequent? We would suggest that the department create a definition of "school employee" that would indicate who is to be included and excluded. For example, a definition could state that a school employee is an individual employed by a school, and would include (if it is the department's intention) an independent contractor and employees and would exclude an individual who has no direct contact or routine interaction with students. The creation of a definition would help to eliminate confusion among the school personnel who will be expected to comply with the provisions of Chapter 27.

Also confusing is the issue of whether volunteers are to be included under the requirements. According to the preamble that was published in the *Pennsylvania Bulletin*, "the term staff is intended to include all individuals that may work in school, including volunteers," yet nowhere

in the regulations does it mention volunteers. If indeed volunteers are to be included, other questions must be raised. Volunteers come into school buildings at various times throughout the school year to help with classroom activities, field trips, social and sporting events and many other functions. It would be difficult, at best, to expect school personnel to medically monitor these people and require them to comply with exclusion and readmission requirements that are more properly written to focus on health and wellness issues related to students and school employees.

PSBA suggests that volunteers should not be included under the proposal, and should be specifically excluded in any definition of school employee/staff. Instead, the proposal could include language that emphasizes the authority of school personnel to prohibit volunteers from working with staff and students if it is believed that a health risk exists.

Another area of the proposal that we believe should be clarified is language regarding the readmission of pupils and staff. Sections 27.71 and 27.73 state that no one may be readmitted "until the school nurse or, in the absence of a school nurse, a physician" verifies that the person has recovered or is noninfectious. We suggest that the words "in the absence of a school nurse" be deleted because, as it now reads, a physician may make the determination for readmission only if a school nurse is unavailable. Does this mean that no student or school employee may return to school until he or she is examined by a school nurse? Certainly, in the most practical sense, that would present administrative difficulties since most schools do not have a nurse in the building every day. Additionally, the function of school nurses is to focus on the health of students, not employees, on a routine basis.

We also would like to comment on the language in 27.72 (b) that requires schools to maintain records of the exclusion of students and staff. The language here is rather broad, and we believe that some clarification is necessary. Will school districts be required to submit reports to the department? The proposal seems to imply this, but does not specifically state so. Also, does each school district have the authority to determine what an "unusual rate of absenteeism" is and how often it will review its records to make its determination? Finally, we would suggest that the development of guidelines and forms by the department would be helpful in assisting school personnel to comply with these new recordkeeping duties.

We appreciate the opportunity to review and comment on the proposed revisions to Chapter 27. Please contact me if you wish to discuss the issues addressed in this letter.

Sincerely,

Thomas J. Gentzel
Assistant Executive Director
Governmental and Member Relations

PENNSYLVANIA SCHOOL BOARDS ASSOCIATION, INC
774 LIMEKILN ROAD, NEW CUMBERLAND, PA 17070-2398
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FACSIMILE
* * * * *

TO:	FROM:
Robert Nyce **Executive Director**	**Thomas J. Gentzel** Assistant Executive Director Governmental and Member Relations
COMPANY:	DATE:
IRRC	**JUNE 26, 2000**
FAX NUMBER:	TOTAL NO. OF PAGES INCLUDING COVER:
717-783-2664	**4**

NOTES/COMMENTS:

Enclosed are comments from the Pennsylvania School Boards Association regarding proposed revisions to Title 28, Part II, Chapter 27 on communicable and noncommunicable diseases that was published in the May 27 issue of the Pennsylvania Bulletin. (I am sending the original to you in today's mail.)

Please contact me if you have any questions or concerns.

Original: 2119

PENNSYLVANIA
SCHOOL BOARDS
ASSOCIATION, INC.

774 LIMEKILN ROAD, NEW CUMBERLAND, PA 17070-2398 / (717) 774-2331 / FAX (717) 774-0718

June 26, 2000

James T. Rankin, Jr., Director
Division of Communicable Disease Epidemiology
Department of Health
P.O. Box 90
Harrisburg, PA 17108

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First, in order to abate any confusion that may occur in the interpretation of the regulations, we recommend that the department clearly define what adults are affected by the provisions. Section 27.71 refers to "a staff person who has contact with pupils." Does that mean only teachers and administrators, or does it include custodians, cafeteria workers and bus drivers? Does it include contractors or employees of contractors? What does "contact with pupils" mean; that is, what kind of contact and/or how frequent? We would suggest that the department create a definition of "school employee" that would indicate who is to be included and excluded. For example, a definition could state that a school employee is an individual employed by a school, and would include (if it is the department's intention) an independent contractor and employees and would exclude an individual who has no direct contact or routine interaction with students. The creation of a definition would help to eliminate confusion among the school personnel who will be expected to comply with the provisions of Chapter 27.

Also confusing is the issue of whether volunteers are to be included under the requirements. According to the preamble that was published in the *Pennsylvania Bulletin*, "the term staff is intended to include all individuals that may work in school, including volunteers," yet nowhere

in the regulations does it mention volunteers. If indeed volunteers are to be included, other questions must be raised. Volunteers come into school buildings at various times throughout the school year to help with classroom activities, field trips, social and sporting events and many other functions. It would be difficult, at best, to expect school personnel to medically monitor these people and require them to comply with exclusion and readmission requirements that are more properly written to focus on health and wellness issues related to students and school employees.

PSBA suggests that volunteers should not be included under the proposal, and should be specifically excluded in any definition of school employee/staff. Instead, the proposal could include language that emphasizes the authority of school personnel to prohibit volunteers from working with staff and students if it is believed that a health risk exists.

Another area of the proposal that we believe should be clarified is language regarding the readmission of pupils and staff. Sections 27.71 and 27.73 state that no one may be readmitted "until the school nurse or, in the absence of a school nurse, a physician" verifies that the person has recovered or is noninfectious. We suggest that the words "in the absence of a school nurse" be deleted because, as it now reads, a physician may make the determination for readmission only if a school nurse is unavailable. Does this mean that no student or school employee may return to school until he or she is examined by a school nurse? Certainly, in the most practical sense, that would present administrative difficulties since most schools do not have a nurse in the building every day. Additionally, the function of school nurses is to focus on the health of students, not employees, on a routine basis.

We also would like to comment on the language in 27.72 (b) that requires schools to maintain records of the exclusion of students and staff. The language here is rather broad, and we believe that some clarification is necessary. Will school districts be required to submit reports to the department? The proposal seems to imply this, but does not specifically state so. Also, does each school district have the authority to determine what an "unusual rate of absenteeism" is and how often it will review its records to make its determination? Finally, we would suggest that the development of guidelines and forms by the department would be helpful in assisting school personnel to comply with these new recordkeeping duties.

We appreciate the opportunity to review and comment on the proposed revisions to Chapter 27. Please contact me if you wish to discuss the issues addressed in this letter.

Sincerely,

Thomas J. Gentzel
Assistant Executive Director
Governmental and Member Relations

PENNSYLVANIA FIRE & EMERGENCY SERVICES INSTITUTE

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Original: 2119
June 26, 2000

Dr. James Rankin
Division of Communicable Diseases
PA Dept. of Health
PO Box 90
Harrisburg PA 17108

Dear Dr. Rankin:

I am writing on behalf of the PA Hepatitis C Coalition regarding regulations 30 Pa.B. 2715, specifically as it relates to reporting of hepatitis C. As you are aware, hepatitis C is not presently reportable in Pennsylvania; therefore the number of citizens in the Commonwealth infected with this disease is an estimate based on CDC statistics (216,000). Until this disease is reportable, these numbers demonstrate the need for more inclusive data so we accurately assess the public health threat to Pennsylvanians.

As you are aware, the proposed regulations add hepatitis C to the list of reportable diseases. If this list includes chronic, as well as acute, cases of hepatitis C, then we support the regulation. If the regulations limit the reporting to acute only, then we do not support the regulation and ask that you recommend reporting of "chronic" to the list. Additionally, we cannot afford to wait years for this reporting to be implemented through a long regulatory process.

As you know, the number of people who die annually from hepatitis C continues to rise. We cannot afford to let this issue languish in a slow regulatory process, while people today aren't even aware that they're carrying this disease. This silent epidemic can remain silent no longer.

We look forward to your continued leadership on this issue. As time passes, so does the progression of this disease.

Sincerely,

John Brenner
Executive Director

HAP

Original: 2119

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

June 23, 2000

Mr. John McGinley, Jr.
Chairperson
Independent Regulatory Review Commission
333 Market Street
14th Floor
Harrisburg, PA 17101

RE: Title 28. Health and Safety, Part III. Prevention of Diseases, Chapter 27. Communicable and Noncommunicable Diseases

Dear Mr. McGinley:

The Hospital & Healthsystem Association of Pennsylvania (HAP), on behalf of its approximately 250 member institutions, comprised of 125 stand-alone hospitals and another +120 hospitals that comprise 32 health systems across the state, welcomes the opportunity to comment on the proposed regulations dealing with the communicable and noncommunicable disease reporting and control of disease transmission. HAP commends the Department of Health for tackling the job of updating this set of regulations. HAP would like to bring the following concerns and/or recommendations to the attention of the Department of Health:

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imposition of fines and possible imprisonment of isolated patients with tuberculosis will not serve as a deterrent to such behavior, especially if the individual is destitute or homeless and that such a regulation will neither be enforceable nor is in the best interest of quality patient care. Hospitals have described a series of issues that they confront when such an individual leaves their organization against medical advice. Hospital staff and security cannot detain these individuals. Alternatively, when hospitals report such occurrences to law enforcement authorities, they indicate that law enforcement officials will not detain or arrest these individuals. Furthermore, it is unclear whether such incidents should be brought to the attention of local or state health authorities for possible intervention. HAP recommends that the Department of Health provide some guidance that outlines the procedure that providers should follow when a patient under their care and covered under the provisions of these regulations leaves their organization against medical advice.

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  (1) include crytosporidiosis, histoplasmosis, meningitis, toxoplasmosis, and yellow fever on the list of reportable diseases for clinical laboratories;

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HAP

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(5) clarify what the Department of Health expects to be reported by its identification of an "unusual cluster of isolates" in the list of reportable diseases by clinical laboratories since the term "unusual" may mean something different depending upon the type of disease; and

(6) remove varicella (chickenpox) from the reportable disease list for health care facilities and health care practitioners until the Department of Health determines whether such reporting is warranted based upon trends in the information initially reported by clinical laboratories. By including a three-year time frame, the department already presupposes that varicella cases will need to be reported by health care facilities and practitioners. Further, HAP suggests that the reporting of varicella by health care facilities and practitioners be delayed until such time that varicella immunization is a required vaccine for entry into school. Although the department has indicated that health care facilities and practitioners would not need to report varicella cases until three years after the adoption of these regulations, there is the possibility that varicella vaccination may still not be a required vaccination by that time. It is HAP's understanding that the Department of Health would like to understand the efficacy rate of the varicella vaccine. Therefore, it seems appropriate that health care facility and practitioner reporting of such cases should not occur until such time that the vaccine becomes mandatory for admittance to school.

- § 27.21(b)(1) indicates that a health care facility or health care practitioner is not required to report a case if that health care practitioner or health care facility has reported the case previously. HAP requests that the department consider clarifying that a health care facility is not required to report a case if the facility's clinical laboratory has already reported the case. Hospitals have indicated that they do not report a case if their clinical laboratory has already reported that case to local or state health care authorities.

- The regulations as proposed by the Department of Health indicate that health care facilities or practitioners need to report diseases to the local health care authority in which the patient resides. We believe it would be much easier to contact their local health authority to provide the relevant case information,

HAP

rather than having each organization try to determine which local health authority they should be reporting that information to in Pennsylvania. The local health authority could in turn determine where to appropriately refer that case information. Many hospital infection control practitioners indicated that this is how they are currently handling case reports for those patients who reside in another county or city that has its own health department.

- In reviewing all of the various requirements where case reports for various diseases should be relayed, it quickly becomes apparent that there are many reasons why reports are not filed with appropriate agencies. For instance, a health care facility and practitioner must report cases of sexually transmitted diseases to the appropriate health authority of the county or municipal health department when the patient resides in a city or county that has its own health department. Otherwise, these reports need to be transmitted to the Division of Tuberculosis and Sexually Transmitted Diseases, Bureau of Communicable Diseases, Department of Health. Alternatively, reports of metabolic diseases, including maple syrup urine disease, phenylketonuria, primary congenital hypothyroidism and sickle cell hemogloinopthies do not need to be reported to local or municipal health authorities, but do need to be directed to yet another bureau, the Division of Maternal and Child Health, Bureau of Family Health. There are other requirements for reporting lead poisoning and other diseases. HAP strongly recommends that the Department of Health consider ways to simplify its disease reporting requirements possibly by creating a clearinghouse where reports could be submitted by health care facilities and practitioners that could in turn be transmitted to all the relevant agencies that need that information. In the meantime, HAP recommends that the Department of Health create easy to use one-page laminated reference sheets that permit health care facility personnel and practitioners to identify where disease reports should be transmitted.

Subchapter C. Quarantine and Isolation; Communicable Diseases in Children and Staff Attending Schools and Child Care Group Settings

- It appears that this subchapter is intended to deal with the quarantine and isolation of persons in the community, particularly since the Department of Health deleted an existing section, titled isolation within hospitals. HAP requests the Department of Health clarify the intent of this subchapter as it relates to hospitals in the regulation's preamble or indicate in the regulations under what circumstances health care facilities need to contact local health officials to confer about matters related to quarantine and isolation. Hospitals routinely adhere to

HAP

Centers for Disease Control (CDC) standards related to isolation of patients and the transporting of those patients throughout the health care facility or other health care facilities in and outside of Pennsylvania without involving local or state health officials. HAP does not believe that the Department of Health needs to get calls from hospitals on matters related to isolation that are considered routine.

- HAP requests that the department reconcile differences in its regulations dealing with exclusion of students and staff from attending schools and child care settings with the CDC Personnel Health Guidelines published in the September 8, 1997 *Federal Register* (Volume 62, pages 47275-47320) that deal specifically with the prevention of nosocomial transmission of selected infections. In reviewing the Department of Health regulations and the CDC guidelines, there are considerable differences in the length of time persons should be restricted from returning to school or child care, in how asyptomatic exposed personnel should be managed or in how exposed persons without disease immunity should be handled. The same CDC Personnel Health Guidelines can also be found in the *American Journal of Infection Control* (Volume 26, pages 289-354). HAP did forward these guidelines to the Department of Health when comments to the stakeholder draft were submitted for the Department of Health's consideration.

Subchapter D. Sexually Transmitted Diseases, Tuberculosis and Other Communicable Diseases

- HAP continues to have serious concerns about §27.97, which deals with the treatment of minors. The current regulations allow for a person under the age of 21, infected with a venereal disease (sexually transmitted disease), to be given appropriate treatment by a physician without the consent of his/her parents or guardian. The proposed revisions significantly broaden the intent by allowing for any individual under 21 years of age to give consent for medical and other health services to determine the presence of or to treat a sexually transmitted disease and any other reportable disease, infection or condition without another person's consent. As written, this would mean that a minor could give consent for the diagnostic workup of suspected cancer and cancer treatment without parental consent. First, there is obvious concern whether minors of a certain age can appropriately give informed consent to diagnosis, evaluation and treatment. Second, health care facilities and practitioners do not engage and are not likely to engage in the care of minors without obtaining informed consent from the minor's parent or guardian. Third, the original regulations were developed in a different cultural climate where there was a significant stigma attached to the acquisition of a venereal disease to the point where individuals did not seek treatment. While HAP recognizes the Department of Health's need to address an individual's

HAP

access to health care services for the treatment of diseases that threaten the public's health, the Department of Health also needs to be cognizant of parental rights and responsibilities in consenting to the provision of health services to children and adolescents. HAP again requests that this section undergo further legal review since it has been made exceptionally broad in allowing for evaluation and treatment of all reportable diseases, infections or conditions in a minor without parental consent and seems to ensure immunity to a practitioner if he/she evaluates and treats a minor with a reportable disease, infection or condition without parental consent.

Subchapter E. Selected Procedures for Preventing Disease Transmission

- HAP again requests that the Department of Health reconcile differences in this subchapter dealing with §27.153 restrictions on food handlers, §27.154 restriction on caregivers in a child care setting, and §27.155 restriction on health care practitioners with the CDC Personnel Health Guidelines published in the September 8, 1997 *Federal Register* (Volume 62, pages 47275-47320) that deal specifically with the prevention of nosocomial transmission of selected infections. In particular, HAP asks that the Department of Health reconcile the discrepancies with respect to hepatitis A and diarrhea, including the fact that use of the term itself may be outmoded and should be replaced by using the term gastroenteritis.

- As mentioned previously, Department of Health requirements related to special requirements for measles, §27.160, should also be reconciled for discrepancies with the aforementioned CDC Personnel Health Guidelines.

HAP strongly suggests that the Department of Health provide education sessions across the state about disease reporting, particularly since there are differences in how various county health departments or other local health authorities work with health care facilities and practitioners in disease reporting, the presence or absence of county health departments dictates the manner in which diseases are reported, and the special requirements for the reporting of certain diseases, infections or conditions that exist. It would be beneficial if the Department of Health could discuss its plans, if any, for electronic submission of reports, review the forms used for disease reporting, and provide reporting contacts and phone numbers for each county as appropriate to assist health care facilities, health care practitioners and clinical laboratories in fulfilling their reporting requirements as outlined in the regulations. HAP also requests that the Department of Health give consideration to including a hospital-based infection control practitioner on department task forces or the Advisory Health Board of the department to ensure that the organization perspective related to disease surveillance is considered, and appropriately addressed.

HAP

Mr. John McGinley
June 23, 2000
Page 8

Again, HAP appreciates the opportunity to comment on the Department of Health's proposed regulations addressing the reporting of communicable and noncommunicable diseases and the Department of Health's efforts in attempting to significantly revise and update these regulations. HAP believes that our suggestions and recommendations will improve or clarify the revisions that the Department of Health is proposing be made to the existing set of regulations. HAP looks forward to working with the Department of Health in areas of infection control and epidemiology to benefit community health and protect the public from harmful diseases or infections.

If you have any questions about the issues or suggestions outlined in this letter, please feel free to contact Lynn Gurski-Leighton, Director, Clinical Services, HAP at 717-561-5308 or by email at lgleighton@hap2000.org.

Sincerely,

Paula A. Bussard

PAULA A. BUSSARD
Senior Vice President, Policy and Regulatory Services

PAB/zf

c: Howard A. Burde, Esq., Deputy General Counsel, Office of General Counsel
Helen K. Burns, Deputy Secretary for Health Planning and Assessment, DOH
Vincent J. Hughes, Minority Chair, Senate Public Health & Welfare Committee
Lori McLaughlin, Esq., Chief Counsel, Department of Health
Harold F. Mowery Jr., Chair, Senate Public Health & Welfare Committee
Dennis M. O'Brien, Chair, House Health & Human Services Committee
Frank L. Oliver, Minority Chair, House Health & Human Services Committee
James T. Rankin, Jr., DVM, MPH, PhD

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

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FAX TRANSMISSION

9 page(s), including cover sheet

TO: James Smith, IRRC

FAX: 783-2664

FROM: Zona M. Fisher

DATE: June 26, 2000

SUBJECT: Comments on Proposed Regulations

MESSAGE:

Attached please find HAP's comments re Title 28. Health and Safety, Part III. Prevention of Diseases, Chapter 27, Communicable and Noncommunicable Diseases.

HAP

Original: 2119

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

June 23, 2000

James T. Rankin, Jr., DVM, MPH, PhD
Director, Division of Communicable Disease Epidemiology
Department of Health
P.O. Box 90
Harrisburg, PA 17108

RE: Title 28. Health and Safety, Part III. Prevention of Diseases, Chapter 27. Communicable and Noncommunicable Diseases

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Subchapter D. Sexually Transmitted Diseases, Tuberculosis and Other Communicable Diseases

- HAP continues to have serious concerns about §27.97, which deals with the treatment of minors. The current regulations allow for a person under the age of 21, infected with a venereal disease (sexually transmitted disease), to be given appropriate treatment by a physician without the consent of his/her parents or guardian. The proposed revisions significantly broaden the intent by allowing for any individual under 21 years of age to give consent for medical and other health services to determine the presence of or to treat a sexually transmitted disease and any other reportable disease, infection or condition without another person's consent. As written, this would mean that a minor could give consent for the diagnostic workup of suspected cancer and cancer treatment without parental consent. First, there is obvious concern whether minors of a certain age can appropriately give informed consent to diagnosis, evaluation and treatment. Second, health care facilities and practitioners do not engage and are not likely to engage in the care of minors without obtaining informed consent from the minor's parent or guardian. Third, the original regulations were developed in a different cultural climate where there was a significant stigma attached to the acquisition of a venereal disease to the point where individuals did not seek treatment. While HAP recognizes the Department of Health's need to address an individual's

access to health care services for the treatment of diseases that threaten the public's health, the Department of Health also needs to be cognizant of parental rights and responsibilities in consenting to the provision of health services to children and adolescents. HAP again requests that this section undergo further legal review since it has been made exceptionally broad in allowing for evaluation and treatment of all reportable diseases, infections or conditions in a minor without parental consent and seems to ensure immunity to a practitioner if he/she evaluates and treats a minor with a reportable disease, infection or condition without parental consent.

Subchapter E. Selected Procedures for Preventing Disease Transmission

- HAP again requests that the Department of Health reconcile differences in this subchapter dealing with §27.153 restrictions on food handlers, §27.154 restriction on caregivers in a child care setting, and §27.155 restriction on health care practitioners with the CDC Personnel Health Guidelines published in the September 8, 1997 *Federal Register* (Volume 62, pages 47275-47320) that deal specifically with the prevention of nosocomial transmission of selected infections. In particular, HAP asks that the Department of Health reconcile the discrepancies with respect to hepatitis A and diarrhea, including the fact that use of the term itself may be outmoded and should be replaced by using the term gastroenteritis.

- As mentioned previously, Department of Health requirements related to special requirements for measles, §27.160, should also be reconciled for discrepancies with the aforementioned CDC Personnel Health Guidelines.

HAP strongly suggests that the Department of Health provide education sessions across the state about disease reporting, particularly since there are differences in how various county health departments or other local health authorities work with health care facilities and practitioners in disease reporting, the presence or absence of county health departments dictates the manner in which diseases are reported, and the special requirements for the reporting of certain diseases, infections or conditions that exist. It would be beneficial if the Department of Health could discuss its plans, if any, for electronic submission of reports, review the forms used for disease reporting, and provide reporting contacts and phone numbers for each county as appropriate to assist health care facilities, health care practitioners and clinical laboratories in fulfilling their reporting requirements as outlined in the regulations. HAP also requests that the Department of Health give consideration to including a hospital-based infection control practitioner on department task forces or the Advisory Health Board of the department to ensure that the organization perspective related to disease surveillance is considered, and appropriately addressed.

Again, HAP appreciates the opportunity to comment on the Department of Health's proposed regulations addressing the reporting of communicable and noncommunicable diseases and the Department of Health's efforts in attempting to significantly revise and update these regulations. HAP believes that our suggestions and recommendations will improve or clarify the revisions that the Department of Health is proposing be made to the existing set of regulations. HAP looks forward to working with the Department of Health in areas of infection control and epidemiology to benefit community health and protect the public from harmful diseases or infections.

If you have any questions about the issues or suggestions outlined in this letter, please feel free to contact Lynn Gurski-Leighton, Director, Clinical Services, HAP at 717-561-5308 or by email at lgleighton@hap2000.org.

Sincerely,

Paula A. Bussard

PAULA A. BUSSARD
Senior Vice President, Policy and Regulatory Services

PAB/zf

c: Howard A. Burde, Esq., Deputy General Counsel, Office of General Counsel
Helen K. Burns, Deputy Secretary for Health Planning and Assessment, DOH
Vincent J. Hughes, Minority Chair, Senate Public Health & Welfare Committee
John McGinley, Jr., Chairperson, Independent Regulatory Review Commission
Lori McLaughlin, Esq., Chief Counsel, Department of Health
Harold F. Mowery Jr., Chair, Senate Public Health & Welfare Committee
Dennis M. O'Brien, Chair, House Health & Human Services Committee
Frank L. Oliver, Minority Chair, House Health & Human Services Committee

Original: 2119

American Liver Foundation

Delaware Valley Chapter

June 23, 2000

RECEIVED
2000 JUL 29 AM 8:36
REVIEW COMMISSION

Dr. James Rankin
Division of Communicable Diseases
PA Department of Health
P.O. Box 90
Harrisburg, PA 17108

Dear Dr. Rankin:

I am writing to you on behalf of the Delaware Valley Chapter of the American Liver Foundation regarding regulations 30 Pa.B. 2715. More specifically, as the regulations relate to reporting of Hepatitis C cases in Pennsylvania.

With more than an estimated 216,000 Pennsylvania Residents who have tested positive for the Hepatitis C virus, there needs to be more reputable and inclusive data so that an accurate assessment of the public health threat to Pennsylvanians can be properly evaluated.

It is our opinion that this estimate, based on CDC statistics, is evidence that demonstrates the need for more extensive reporting of Hepatitis C cases. We are proposing that you include Hepatitis C to the list of reportable diseases. If this list includes chronic, as well as acute, cases of hepatitis C, then we support the regulation. If the regulations limit the reporting to include acute only, then we do not support the regulation and ask that you recommend reporting of "chronic" to the list.

Last year, nearly 1,300 individuals died waiting for a liver transplant. Keeping in mind that with the CDC's projection that Hepatitis C cases will more than triple by the year 2010, coupled with the fact that 85% of these cases will develop into long-term liver disease, Cirrhosis or Liver Cancer, we believe this will further impact the demand for liver transplantation. Therefore, we cannot afford to wait years for reporting to be implemented through a long regulatory process.

With people today unaware that they are carrying this disease and the slow regulatory process associated with many proposed regulations such as Regulation 30 Pa.B. 2715, we look forward to your support and leadership on this issue.

This epidemic has remained silent too long. We hope we can look to your support in making the changes necessary in harnessing this "silent killer."

Sincerely,

Debra Kleine
Executive Director

1608 Walnut Street, Suite 1704 • Philadelphia, PA 19103 • 215-545-1688 • Fax 215-545-6564
American Liver Foundation National Headquarters 800 GO-LIVER (800-465-4837)
E-Mail: AMERLVFDN@aol.com

Original: 2119

Pennsylvania
MEDICAL SOCIETY®

June 22, 2000

James T. Rankin, Jr., DVM, MPH, Ph.D.
Director, Division of Communicable Disease Epidemidology
Department of Health
PO Box 90
Harrisburg, PA 17108

Re: Department of Health proposed rulemaking – Reporting of Communicable and Non-communicable Diseases

Dear Dr. Rankin:

I am writing as President of the Pennsylvania Medical Society to offer comments on the Department of Health's proposed rulemaking relative to the reporting of communicable and non-communicable diseases which appeared in the May 27, 2000 Pennsylvania Bulletin.

The Medical Society supports the need for improved disease reporting requirements. We also support a more aggressive educational approach aimed toward improved physician reporting of these diseases. The Society would be pleased to work with the Department to advise physicians of these new requirements. We are concerned that the regulations imply that a physician can be disciplined for failure to report. Threatening criminal prosecution or discipline by the licensure board won't improve the rate of reporting. The Society therefore recommends removal of the reference to disciplinary action for failure to report.

I also want to draw particular attention to §27.32 Reporting AIDS. The Society would strongly recommend the reinstatement of this section which has been proposed for deletion. It should be a requirement for physicians as well as hospitals and other healthcare facilities to report AIDS. While we recognize the Department's desire to include all aspects of AIDS and HIV reporting under a separate regulation currently under consideration, to remove the reporting requirement without the more specific requirement in place could create a situation where there would be no reporting of AIDS --a giant step backward.

The Medical Society is on record as supporting HIV reporting by name just as other communicable diseases are reported. We would hope that the Department will support name reporting in whatever regulations are promulgated with respect to HIV/AIDS reporting.

777 East Park Drive
P.O. Box 8820
Harrisburg, PA 17105-8820

Tel: 717-558-7750
Fax: 717-558-7840
E-Mail: *stat@pamedsoc.org*
www.pamedsoc.org

Specific Comments

§27.21a. Reporting of cases by health care practitioners and health care facilities.

Haemophilus influenzae type B invasive disease. Recommend the deletion of "type B". All Haemophilus influenzae invasive disease is reportable nationally. Even though many clinical laboratories do not conduct serotyping or the results may be delayed, the disease should be reported so that some action is taken.

Hepatitis, viral, including type A and type E. Recommend deletion of the term "including" and the addition of the words "acute and chronic" after "type E". The other types of viral hepatitis are included in the next section (reportable within 5 work days).

(2) The following diseases. . .within 5 work days. . .identified:

Recommend deletion of the following diseases from this list and their inclusion under the list of diseases reportable within 24 hours: Anthrax*, Animal bite**, Arbovirus disease**, Enterohemorrliagic E.Coli**, Legionellosis**, and Smallpox (Variola)*. Additionally, those diseases indicated by a single asterisk "*" should indicate "due to possible bioterrorist attack". Those diseases with 2 asterisks "**" should require action in less than five days.

Hepatitis, viral, including type B, type C, type D, type G. Recommend deletion of "type G" which we don't believe exists and the addition of "Non-A, Non-B".

The following diseases should be added to the list reportable within 5 days;
Creutzfeld Jacob Disease
Streptococcus pneumonic, Drug-Resistant Invasive Disease
Staphylococcus aureus, Vancomycin-Resistant (or Intermediate) Invasive Disease

§27.22 Reporting of cases by clinical laboratories

Arbovirus limited to Eastern, Western and St. Louis encephalitis.

Recommend deletion of "limited to" and the addition of the term "Equine" after both "Eastern" and "Western" and the addition of "West Nile" after "St. Louis". As recently experienced in New York, other arboviruses may appear in unexpected places and should be reported so that actions, including mosquito control, can be taken.

Hepatitis, viral, including type A, B, C, D, E, and G.

Recommend deletion of ", and G" which we don't believe exists.

(c) The report shall . . .specified by the Department.

Recommend the addition of the following elements to the report: source of specimen (e.g., serum, CSF, stool, wound), results, range of normal values for the specific test.

§2743a.Reporting by local morbidity reporting offices or outbreaks and selected diseases.

"(4) (b)" Recommend renumbering to "(4) (a)"

(3) (b) (2)

Recommend deletion of "hepatitis A" and "meningitis" and the addition of "foodborne" before "botulism".

Recommend the addition of the following:
Arbovirus disease**
Haemophilus influenzae invasive disease in a child under 15 years of age**
Legionellosis**
Smallpox*
*due to possible bioterrorist attack ** action needs to be taken in less than 5 days.

§27.71 Exclusion of pupils and staff for specified diseases and infectious conditions.

Recommend the addition of the following:

(16) Neisseria meningitidis invasive diseases. Until made noninfective by a course of rifampin or other drug which is effective against the nasopharyngeal carrier state of this disease, or otherwise shown to be noninfective. Similar language found under §27.76 for child care group settings and is equally applicable in school settings.

§27.76. Exclusion and readmission of children and staff in child care group settings.

Recommend deletion of "(8) Exposure to . . .influenzae disease. . ."and "(9) Exposure to meningococial disease". There is no reason to exclude children or staff members from the child care group setting relative to these diseases.

§27.98. Prophylactic treatment of newborns.

Recommend the addition of the following language "or if in the opinion of the attending physician the treatment is not advisable" before "prophylactic treatment shall be withheld."

§27.99. Prenatal examination for hepatitis B.

Recommend the deletion of "(b). . .if the parent or guardian. . . the parent or guardian." It is unlikely that a parent or guardian would object to this treatment and if so, it seems likely that such objection could be challenged in court.

Subchapter E. SELECTED PROCEDURES FOR PREVENTING DISEASE TRANSMISSION

§17.151. Restrictions on the donation of blood, blood products, tissue, sperm, and ova.

Recommend the addition of the phrase "or suspected" after "known" in subsection (a). This would prevent donation of organs or tissue before confirmation of an infection.

Recommend the addition of language "from a person known or suspected of being infected with the causative agent of a reportable disease" before "for donation" and the addition of "and" before "without obtaining". If a donor is infected and prohibited from donating, the recipient agency should be prohibited from accepting the donation. Screening tests would prevent donations from carriers of hepatitis B and C and HIV but not other reportable diseases.

DISPOSITION OF EFFECTS AND REMAINS OF INFECTED PERSONS

§27.201 Disposition of articles exposed to contamination.

Recommend addition of "smallpox (Variola)" before "anthrax". This would reflect the potential for use of this agent by terrorists.

On behalf of the Pennsylvania Medical Society, I would like to thank the Department for its efforts to revise and update the Commonwealth's reporting requirements related to communicable and noncommunicable diseases. I hope you will consider the Society's comments. Please contact Mr. Donald McCoy, the Society's Director of Policy and Regulatory Affairs, if you have any questions regarding the Society's comments.

Sincerely,

Donald H. Smith, MD
President

CC: The Honorable Robert Zimmerman, Secretary of Health
Independent Regulatory Review Commission

DNM/doc/cor/Rankin

Original: 2119

Pennsylvania MEDICAL SOCIETY®

June 22, 2000

James T. Rankin, Jr., DVM, MPH, Ph.D.
Director, Division of Communicable Disease Epidemidology
Department of Health
PO Box 90
Harrisburg, PA 17108

Re: Department of Health proposed rulemaking – Reporting of Communicable and Non-communicable Diseases

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Sincerely,

Donald H. Smith, MD
President

CC: The Honorable Robert Zimmerman, Secretary of Health
Independent Regulatory Review Commission

DNM/doc/cor/Rankin

CH 27

Original: 2119

PENNSYLVANIA

June 21, 2000

James Rankin, DVM MPH PhD
Division of Communicable Diseases
PA Dept. of Health
PO Box 90
Harrisburg, PA 17108

Dear Dr. Rankin:

I am writing on behalf of the PA Hepatitis C Coalition regarding regulations 30 Pa.B. 2715, specifically as it relates to reporting of hepatitis C. As you are aware, hepatitis C is not presently reportable in Pennsylvania; therefore the number of citizens in the Commonwealth infected with this disease is an estimate based on CDC statistics (216,000). Until this disease is reportable, these numbers demonstrate the need for more inclusive data so we accurately assess the public health threat to Pennsylvanians.

As you are aware, the proposed regulations add hepatitis C to the list of reportable diseases. If this list includes chronic, as well as acute, cases of hepatitis C, then we support the regulation. If the regulations limit the reporting to acute only, then we do not support the regulation and ask that you recommend reporting of "chronic" to the list. Additionally, we cannot afford to wait years for this reporting to be implemented through a long regulatory process.

As you know, the number of people who die annually from hepatitis C continues to rise. We cannot afford to let this issue languish in a slow regulatory process, while people today aren't even aware that they're carrying this disease. This silent epidemic can remain silent no longer.

We look forward to your continued leadership on this issue. As time passes, so does the progression of this disease.

Sincerely,

Kathi Cullari
Project Director
PA Hepatitis C Coalition

Enclosure

1999 Population by County and Estimated Hepatitis C Virus (HCV) Incidence

Pennsylvania

County	1999 Population	Estimated # of HCV Cases
Adams	87,697	1,579
Allegheny	1,256,806	22,623
Armstrong	73,001	1,314
Beaver	182,687	3,288
Bedford	49,699	895
Berks	358,211	6,448
Blair	129,937	2,339
Bradford	62,146	1,119
Bucks	594,047	10,693
Butler	172,522	3,105
Cambria	153,766	2,768
Cameron	5,571	100
Carbon	58,759	1,058
Centre	132,190	2,379
Chester	430,001	7,740
Clarion	41,651	750
Clearfield	80,732	1,453
Clinton	36,774	662
Columbia	63,674	1,146
Crawford	89,109	1,604
Cumberland	210,663	3,792
Dauphin	245,576	4,420
Delaware	541,502	9,747
Elk	34,344	618
Erie	276,993	4,986
Fayette	143,775	2,588
Forest	4,938	89
Franklin	128,812	2,319
Fulton	14,616	263
Greene	42,072	757
Huntingdon	44,753	806
Indiana	87,831	1,581
Jefferson	46,086	830
Juniata	22,204	400
Lackawanna	206,520	3,717
Lancaster	460,035	8,281
Lawrence	94,508	1,701
Lebanon	117,856	2,121
Lehigh	299,855	5,397
Luzerne	312,000	5,616
Lycoming	116,709	2,101
McKean	45,987	828
Mercer	121,458	2,186
Mifflin	46,793	842
Monroe	128,541	2,314
Montgomery	724,087	13,034
Montour	17,571	316
Northampton	259,736	4,675
Northumberland	93,163	1,677
Perry	44,280	797
Philadelphia	1,417,601	25,517
Pike	41,357	744
Potter	17,115	308
Schuylkill	148,788	2,678
Snyder	37,875	682
Somerset	80,028	1,441
Sullivan	6,038	109
Susquehanna	42,190	759
Tioga	41,657	750
Union	40,546	730
Venango	57,562	1,036
Warren	43,505	783
Washington	204,888	3,688
Wayne	46,080	829
Westmoreland	370,658	6,672
Wyoming	29,298	527
York	376,586	6,779
Pennsylvania	**11,994,016**	**215,892**

Population Figures from U.S. Census Bureau Website
Estimated HCV Incidence based on the Centers for Disease Control estimated Prevalence Rate of 1.8%

Original: 2119

The City of YORK PENNSYLVANIA

Mayor Charles H. Robertson

DIVISION OF COMMUNITY AFFAIRS

Director's Office
849-2292

Health
849-2252

Housing Services
849-2264

Planning & Zoning
849-2307

Permits/Licensing
849-2256

DIVISION OF PUBLIC SERVICES

Director's Office
849-2245

Building/Electrical Maintenance
845-9351

Environmental Services
849-2245

Highway Maintenance
849-2320

Recreation & Parks
854-1587

June 19, 2000

James T. Rankin, Jr., D.V.M., M.P.H., Ph.D.
Director
Division of Communicable Disease Epidemiology
Pennsylvania Department of Health
P.O. Box 90
Harrisburg, PA 17108

Dear Jim:

On further review I have two additional items that I would like to add to my previous comments concerning proposed regulatory changes on disease reporting as published in the Pennsylvania Bulletin, Volume 30, Number 22, Saturday, May 27, 2000.

1. p. 2734:
§ 27.22 Reporting of cases by clinical laboratories.
(b) The diseases, infections and conditions to be reported include the following:
Add "CD-4 count of 500 cells per microliter or less"

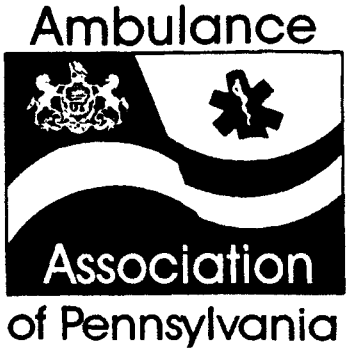
2. AIDS reporting (**§27.32**) has been deleted except for by physicians (**§27.21**). I strongly recommend that AIDS reporting be reinstated as a requirement for not only physicians but also hospitals, health care facilities and institutions. Multiple reporting sources are advantageous and necessary. Duplication of reporting is welcome in order to promote completeness.

Your consideration of these additional comments is greatly appreciated.

Sincerely yours,

David L. Hawk, M.D., M.P.H.
Director
York City Bureau of Health

Original: 2119



June 20, 2000

James T. Rankin, Jr., DVM, MPH, Ph.D.
Director, Division of Communicable Disease - Epidemiology
PA Department of Health
P.O. Box 90
Harrisburg, PA 17108

Dear Dr. Rankin:

On behalf of the Ambulance Association of PA (AAP), we have reviewed the proposed rulemaking for Title 28, Chapter 27 Communicable and Noncommunicable Diseases and have the following comments.

According to the definition of health care practitioner those individuals certified by the DOH would be included therefore the definition would include first responders, EMT's, prehospital registered nurses and paramedics. However, based on the specialized training provided to these individuals they would not necessarily be able to diagnose the listed diseases for reporting. This reporting requirement for EMS personnel cannot be accomplished without a revision to the existing training programs. It is important to note that these health care practitioners treat patients and then deliver them to DOH approved receiving facilities (hospitals). Would the emergency department staff at the hospital appropriately handle the reporting aspect? Is there a way to exclude those individuals identified in the EMS Act from this provision or provide a specific immunity protection from the reporting requirement?

The defined health care practitioner would also be required to report any treatment provided to cancer patients. It is our understanding that this would not include patients who were previously diagnosed. However, this treatment reporting requirement would be confusing to EMS providers who may not know the complete history of the patient nor would the providers be able to diagnose cancer.

In reference to the section regarding "restrictions on health care practitioners" the last condition listed (6) diarrhea is a concern to the association. We understand the potential infectious nature of diarrhea however the description seems to suggest an evaluation by a physician prior to returning to work. Is there a more comprehensive way to describe a potentially infectious case of diarrhea vs. the common one-day condition related to a known strain of influenza? Perhaps an expansion of the word "resolved" would provide the needed clarity.

Thank you for the opportunity to comment. Should you require any further clarity regarding our comments, please contact our office at 717-691-8995.

Sincerely,

Barry Albertson, President
Ambulance Association of PA
P. O. Box 927
Mechanicsburg, PA 17055

BA/jmk