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Minutes of the July 7-8, 2008 **Meeting of the Ohio State Board of Pharmacy**

Monday, July 7, 2008

10:00 a.m. The Ohio State Board of Pharmacy convened in Room East B, 31st Floor, of the Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio, with the following members present:

Nathan S. Lipsyc, R.Ph., *President*; Elizabeth I. Gregg, R.Ph., *Vice-President*; Donald M. Casar, R.Ph.; Barton G. Kaderly, Public Member; Richard F. Kolezynski, R.Ph.; Deborah A. Lange, R.Ph.; Heather L. Pasquale, R.Ph.; and Jerome J. Wiesenbahn, R.Ph.

Also present were William T. Winsley, *Executive Director*; Timothy Benedict, *Assistant Executive Director*; William McMillen, *Licensing Administrator*; Mark Keeley, *Legislative Affairs Administrator*; Chris Reed, *Compliance Supervisor*; David Rowland, *Legal Affairs Administrator*; Danna Droz, *Prescription Drug Monitoring Program Director*; and Sally Ann Steuk, *Assistant Attorney General*.

President Lipsyc administered the new Board Member Oath of Office to Donald M. Casar, R.Ph.; Barton G. Kaderly, Public Member; and Deborah A. Lange, R.Ph.

OATH OF NEW MEMBER

I, Donald M. Casar, as a Member of the Ohio Board of Pharmacy do solemnly swear to uphold the Constitution of the United States and the State of Ohio; to impartially enforce the laws governing the profession of pharmacy and the legal distribution of drugs in the state of Ohio; and carry out the responsibilities of the Board as mandated by the laws of the state of Ohio without bias or prejudice, so help me God.

OATH OF NEW MEMBER

I, Barton G. Kaderly, as a Member of the Ohio Board of Pharmacy do solemnly swear to uphold the Constitution of the United States and the State of Ohio; to impartially enforce the laws governing the profession of pharmacy and the legal distribution of drugs in the state of Ohio; and carry out the responsibilities of the Board as mandated by the laws of the state of Ohio without bias or prejudice, so help me God.

OATH OF NEW MEMBER

I, Deborah A. Lange, as a Member of the Ohio Board of Pharmacy do solemnly swear to uphold the Constitution of the United States and the State of Ohio; to impartially enforce the laws governing the profession of pharmacy and the legal distribution of drugs in the state of Ohio; and carry out the responsibilities of the

Board as mandated by the laws of the state of Ohio without bias or prejudice, so help me God.

10:15 a.m. Mrs. Gregg moved that the Board go into Executive Session for the purpose of the investigation of complaints regarding licensees and registrants pursuant to Section 121.22(G)(1) of the Ohio Revised Code and to confer with an attorney for the Board regarding pending or imminent court action pursuant to Section 121.22(G)(3) of the Ohio Revised Code. The motion was seconded by Mr. Wiesenhahn and a roll-call vote was conducted by President Lipsyc as follows: Casar – *yes*; Gregg – *yes*; Kaderly – *yes*; Kolezynski – *yes*; Lange – *yes*; Pasquale – *yes*; and Wiesenhahn – *yes*.

10:21 a.m. Mr. Braylock arrived and joined the Executive Session in progress.

10:42 a.m. Mrs. Gregg left the meeting prior to the discussion of a matter from which she had recused herself.

11:17 a.m. Mrs. Gregg returned to the Executive Session.

11:32 a.m. The Executive Session ended and the meeting was opened to the public.

R-2009-001 Mr. Braylock moved that the settlement offer in the matter of **Joseph Lee Baumgartner**, R.Ph. (03-2-12607), Oak Harbor, Ohio, be denied. The motion was seconded by Mr. Wiesenhahn and approved by the Board: *Aye* – 8.

R-2009-002 Mr. Braylock moved that a counter offer more acceptable to the Board be made in the matter of **Cardinal Health 110, Inc.** Mr. Kolezynski seconded the motion and it was approved by the Board: *Aye* – 7 *Recused* – 1 (*Gregg*).

R-2009-003 Having reviewed a letter from attorney Jeffrey Smalldon, representing suspended pharmacist **William Merle Preston** (03-3-21668), Ada, Ohio, Mrs. Gregg moved that the Board find that Mr. Preston had met the requirements of his Board order in a manner acceptable to the Board and that his pharmacist identification card may be reinstated. The motion was seconded by Mr. Casar and approved by the Board: *Aye* – 8.

Mrs. Droz discussed the Prescription Drug Monitoring Program with the Board.

11: 56 a.m. The Board recessed for lunch.

1:02 p.m. The Board reconvened with all members present.

Mr. Keeley presented the Legislative Report, and then distributed the 2008 Rules for Review to be discussed by the Board on Tuesday, July 8.

1:42 p.m. The Board recessed briefly.

1:56 p.m. Mr. Rowland reviewed Board policies and procedures with the Board members.

2:52 p.m. Mrs. Gregg moved that the Board go into Executive Session for the purpose of discussing personnel matters pursuant to Section 121.22(G)(1) of the Ohio Revised Code. The motion was seconded by Mr. Kolezynski and a roll-call vote was conducted by President Lipsyc as follows: Braylock – *yes*; Casar – *yes*; Gregg – *yes*; Kaderly – *yes*; Kolezynski – *yes*; Lange – *yes*; Pasquale – *yes*; and Wiesenhahn – *yes*.

3:26 p.m. The Executive Session ended and the meeting was opened to the public.

Mr. Braylock said there was no Nursing Board Committee on Prescriptive Governance Report this month.

Mr. Winsley said there was no Medical Board Physician Assistant Policy Committee meeting report this month.

Because Kevin Mitchell was not reappointed to the Board, he could not continue as the Pharmacy Board member on the Medical Board's Physician Assistant Policy Committee (PAPC). Therefore, after discussion, President Lipsyc appointed Board member Deborah Lange to replace Mr. Mitchell as the Board's representative on the PAPC.

3:27 p.m. The Board recessed for the day.

Tuesday, July 8, 2008

9:00 a.m. The Board reconvened in Room East B, 31st Floor, of the Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio, with the following members present:

Nathan S. Lipsyc, R.Ph., *President*; Elizabeth I. Gregg, R.Ph., *Vice-President*; Gregory Braylock, R.Ph.; Donald M. Casar, R.Ph.; Richard F. Kolezynski, R.Ph.; Deborah A. Lange, R.Ph.; Heather L. Pasquale, R.Ph.; and Jerome J. Wiesenbahn, R.Ph.

9:05 a.m. Mr. Kaderly arrived.

9:10 a.m.

R-2009-004

After discussion, Mrs. Gregg moved that the Board minutes of June 2-4, 2008, be approved as amended. Ms. Pasquale seconded the motion and it was approved by the Board: *Aye* – 8.

Mr. Keeley began to review with the Board the proposed new and amended rules to be approved for final filling at the August, 2008 meeting.

10:00 a.m. New Board members Casar, Kaderly and Lange left the meeting to have their photo IDs made.

The Board recessed briefly.

10:38 a.m. The Board reconvened and Mr. Benedict said there was no Medical Board Prescribing Committee Report this month.

R-2009-005

The Board considered a request for an exemption to Ohio Administrative Code Rule 4729-5-10 (Prescription pick-up station) received for the following sites:

Teregen Laboratories, Willoughby, Ohio (02-1235150)
Various Physician Offices on the letter of request

After discussion, Mrs. Gregg moved that the Board approve the request as long as the parties to the request comply with the requirements in the rule for such an exemption. The motion was seconded by Mr. Braylock and approved by the Board: *Aye* – 5.

10:41 a.m. The new Board members returned and joined the meeting in progress.

R-2009-006

The Board considered a request for an exemption to Ohio Administrative Code Rule 4729-5-10 (Prescription pick-up station) received for the following sites:

Old Brooklyn Pharmacy, Cleveland, Ohio (02-1725950)
Old Brooklyn Concordia Care, Cleveland, Ohio (02-1861650)

After discussion, Mrs. Gregg moved that the Board approve the request as long as the parties to the request comply with the requirements in the rule for such an exemption. The motion was seconded by Ms. Pasquale and approved by the Board: *Aye* – 8.

R-2009-007 The Board considered a request for an exemption to Ohio Administrative Code Rule 4729-5-10 (Prescription pick-up station) received for the following sites:

MetroHealth-Concordia Care Pharmacy, Cleveland, Ohio (02-1459150)
Concordia Care, Cleveland, Ohio (02-1289600)

After discussion, Mr. Braylock moved that the Board approve the request as long as the parties to the request comply with the requirements in the rule for such an exemption. The motion was seconded by Ms. Lange and approved by the Board: *Aye* – 8.

Mr. Keeley completed the review with the Board of the proposed new and amended rules to be approved for final filling at the August, 2008 meeting.

R-2009-008 After discussion, Mr. Braylock moved that Board pay the annual dues to The National Association of State Controlled Substances Authorities (NASCSA). Mr. Casar seconded the motion and it was approved by the Board: *Aye* – 8.

R-2009-009 Mr. McMillen presented a request from pharmacy intern **Durga Devineni** (06-0-05937) Centerville, Ohio for permission to extend her internship one additional year due to extraordinary circumstances pursuant to Rule 4729-3-04 (Pharmacy Intern Identification Card Renewal). After discussion, Mr. Braylock moved that Ms. Devineni's request be approved with the caveat that no further extensions would be granted. The motion was seconded by Mrs. Gregg and approved by the Board: *Aye* – 6/*Nay* – 2.

Mr. McMillen discussed the case of **Ms. Summer Hafiz**, Dublin, Ohio who has applied for an Ohio pharmacist license by reciprocity. It was decided that she must show a total of 1,500 hours of training before the application will be granted.

R-2009-010 The Board considered a request for an exemption to Ohio Administrative Code Rule 4729-5-11 (Responsible person) requesting that **Gerald Edward Ritzman**, R.Ph. (03-1-09581), Rittman, Ohio, be permitted to be the responsible person for the following sites:

Ritzman Natural Health Pharmacy, Rittman, Ohio (02-0458850)
Ritzman Natural Health Pharmacy, Akron, Ohio (02-0458600)

After discussion, Mr. Casar moved that the Board approve the request for 6 months. The motion was seconded by Ms. Lange and approved by the Board: *Aye* – 8.

12:22 p.m. The Board recessed for lunch.

1:30 p.m. The following candidates for licensure by reciprocity met with members of the Board in Room South A, 31st Floor of the Vern Riffe Center. The candidates introduced themselves and participated in a discussion of pharmacy laws and rules with Mr. McMillen and the Board.

Amanda Beth Bain	<i>Massachusetts</i>
Janice Peterson Glinka	<i>Pennsylvania</i>
Shanna Jo Hager	<i>Iowa</i>
Charles Henry Hayes, III	<i>Missouri</i>
Ryan Joshua Healey	<i>South Carolina</i>
Joseph Thomas Horsfall, II	<i>Indiana</i>
Franklin Joseph Kalisz	<i>West Virginia</i>
Timothy Layne Lakes	<i>Indiana</i>
Bhavin Kantilal Mistry	<i>Pennsylvania</i>
Summer Lee Schwab	<i>Pennsylvania</i>
Shane David Scott	<i>Iowa</i>

Eric N. Sears	<i>West Virginia</i>
Corinne Saulnier Solomon	<i>Hawaii</i>
Richard Carlin Walsh	<i>Illinois</i>
Wesley Zemrak	<i>Maine</i>

The Board reconvened in Room East B with all members present.

1:52 p.m. Mrs. Gregg moved that the Board go into Executive Session for the purpose of the investigation of complaints regarding licensees and registrants pursuant to Section 121.22(G)(1) of the Ohio Revised Code. The motion was seconded by Mr. Kolezynski and a roll-call vote was conducted by President Lipsyc as follows: Braylock – *yes*; Casar – *yes*; Gregg – *yes*; Kaderly – *yes*; Kolezynski – *yes*; Pasquale – *yes*; and Wiesenbahn – *yes*.

2:07 p.m. The Executive Session ended and the meeting was opened to the public.

R-2009-011 Mr. Braylock moved that the Board summarily suspend the license to practice pharmacy belonging to **Scott Wayne Savage**, R.Ph. (03-2-25203), Raleigh, North Carolina, pursuant to Ohio Revised Code 3719.121 (A) and (B). Mrs. Gregg seconded the motion and it was approved by the Board: *Aye* – 8.

R-2009-012 Mr. Benedict announced that the following Settlement Agreement with **Gregory Royce Garner**, R.Ph. (03-1-09514), Dublin, Ohio, had been signed by the respondent and his attorney and would become effective upon the signature of the President and the Assistant Attorney General.

SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY
VOLUNTARY SURRENDER WITH DISCIPLINARY ACTION
PENDING PERMANENT SURRENDER

Docket Number 080618-051

in the matter of:

GREGORY R. GARNER, R.Ph.
6028 Kentigren Court South
Dublin, Ohio 43017

R.Ph. Number 03-1-09514

This Settlement Agreement is entered into by and between Gregory R. Garner and the Ohio State Board of Pharmacy, a state agency charged with enforcing the Pharmacy Practice Act and Dangerous Drug Distribution Act, Chapter 4729. of the Ohio Revised Code.

Gregory R. Garner enters into this Agreement being fully informed of his rights afforded under Chapter 119. of the Ohio Revised Code, including the right to representation by counsel and the right to a formal adjudication hearing on the issues contained herein.

Gregory R. Garner is knowingly and voluntarily acknowledging that, in order to settle the disciplinary charges that would be filed by the Board against him and in order to obviate the need to conduct an administrative hearing to consider possible disciplinary sanctions against Gregory R. Garner's license to practice pharmacy in the State of Ohio, this Agreement is entered into on the basis of the following stipulations, admissions, and understandings:

- (A) The Ohio State Board of Pharmacy is empowered by Section 4729.16 of the Ohio Revised Code to suspend, revoke, place on probation, refuse to grant or renew an identification card, or impose a monetary penalty on the license holder for violation of any of the enumerated grounds.
- (B) Gregory R. Garner neither admits nor denies the allegations pending in the Board's investigation; however, the Board has initiated and conducted an investigation pursuant to the mandate of Sections 3719.18 and 4729.25 of the Ohio Revised Code.
- (C) Gregory R. Garner acknowledges that he has been made aware of the investigation and has not failed to cooperate in said investigation. Gregory R. Garner further acknowledges that he has not been promised or given anything as an inducement to enter into this agreement.

Wherefore, in consideration of the foregoing and mutual promises hereinafter set forth, and in lieu of the filing of formal ADMINISTRATIVE charges and/or holding a 119. hearing at this time, Gregory R. Garner knowingly and voluntarily **SURRENDERS PERMANENTLY TO THE STATE BOARD OF PHARMACY HIS LICENSE AND REGISTRATION TO PRACTICE PHARMACY, WITH DISCIPLINARY ACTION PENDING.**

Gregory R. Garner acknowledges that he has had an opportunity to ask questions concerning the terms of this agreement and that all questions asked have been answered in a satisfactory manner.

Gregory R. Garner waives any and all claims or causes of action he may have against the State of Ohio or the Board, and members, officers, employees, and/or agents of either, arising out of matters which are the subject of this Agreement. Gregory R. Garner waives any rights of appeal pursuant to Chapter 119. of the Ohio Revised Code.

Gregory R. Garner, pursuant to Section 4729.16(B) of the Ohio Revised Code, must return his license to practice (pocket ID card) and registration (wall certificate) to the office of the State Board of Pharmacy within ten days after receipt of this Order unless the Board office is already in possession of both. The identification card and wall certificate should be sent by certified mail, return receipt requested.

This Settlement Agreement shall be considered a public record, as that term is used in Section 149.43 of the Ohio Revised Code, and shall become effective upon the date of the Board President's signature below.

/s/ Gregory R. Garner R.Ph. Date Signed: 06/23/08
Respondent

/s/ Samuel B. Weiner Date Signed: 06/23/08
Attorney for Respondent

/s/ Nathan Lipsyc Date Signed: 07/08/08
President, Ohio State Board of Pharmacy

/s/ Sally Ann Steuk Date Signed: 07/09/08
Ohio Assistant Attorney General

R-2009-013

Mr. Benedict announced that the following Settlement Agreement with **Cardinal Health 110, Inc.** (01-1438400), Findlay, Ohio, had been signed by the respondent's representative and

attorney and would become effective upon the signature of the President and the Assistant Attorney General.

SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY

(Docket Number 080527-048)

in the matter of:

CARDINAL HEALTH 110, INC.

14601 County Road 212

Findlay, Ohio 45840

Ohio Wholesale Distributor of Dangerous Drugs License Number 01-1438400;
Wholesaler of Controlled Substance License Number W-2172

This Settlement Agreement ("Agreement") is entered into by and between Cardinal Health 110, Inc. and the Ohio State Board of Pharmacy ("Board"), a state agency charged with enforcing the Pharmacy Practice Act and Dangerous Drug Distribution Act, Chapter 4729. of the Ohio Revised Code.

Cardinal Health 110, Inc. enters into this Agreement being fully informed of its rights afforded under Chapter 119. of the Ohio Revised Code, including the right to representation by counsel and the right to a formal adjudication hearing on the issues contained herein.

Cardinal Health 110, Inc. is knowingly and voluntarily acknowledging that, in order to settle the disciplinary charges that were filed by the Board against it and in order to obviate the need to conduct an administrative hearing to consider possible disciplinary sanctions against Cardinal Health 110, Inc.'s license to sell controlled substances and dangerous drugs subject to abuse in the State of Ohio, this Agreement is entered into on the basis of the following stipulations, admissions, and understandings:

The Ohio State Board of Pharmacy is empowered by Section 4729.56 of the Ohio Revised Code to suspend, revoke, or refuse to renew any registration certificate issued to a wholesale distributor of dangerous drugs pursuant to section 4729.52 of the Ohio Revised Code or may impose a monetary penalty on the license holder for violation of any of the enumerated grounds.

Cardinal Health 110, Inc. neither admits nor denies the allegations pending in the Board's investigation; however, the Board has initiated and conducted an investigation pursuant to the mandate of Sections 3719.18 and 4729.25 of the Ohio Revised Code.

Cardinal Health 110, Inc. acknowledges that it has been made aware of the investigation and has not failed to cooperate in said investigation.

Wherefore, in consideration of the foregoing and mutual promises hereinafter set forth, and in lieu of holding a 119. hearing at this time, Cardinal Health 110, Inc. knowingly and voluntarily agrees to pay the sum of One Hundred Five Thousand U.S. dollars (\$105,000) within thirty days of the execution by all parties of this Agreement. This sum will be made payable to the "Treasurer, State of Ohio" and mailed to the State Board of Pharmacy, 77 South High Street, 17th Floor, Columbus, Ohio 43266-0320. In addition, as of the effective date of this Agreement, Cardinal Health 110, Inc. shall establish and maintain a Suspicious Order Monitoring (SOM) program as described in Attachment 1 of this Agreement to assist Cardinal Health 110, Inc. in fulfilling its obligations to identify

and report to the Board suspicious orders as required under Rule 4729-9-16(H)(1)(e) of the Ohio Administrative Code.

Cardinal Health 110, Inc. acknowledges that it has had an opportunity to ask questions concerning the terms of this Agreement and that all questions asked have been answered in a satisfactory manner.

Cardinal Health 110, Inc. waives any and all claims or causes of action it may have against the State of Ohio or the Board, and members, officers, employees, and/or agents of either, arising out of matters which are the subject of this Agreement. Cardinal Health 110, Inc. waives any rights of appeal pursuant to Chapter 119. of the Ohio Revised Code.

Subject to the terms of this Agreement, and conditioned upon Cardinal Health 110, Inc's completing in full the payment as described above, the Ohio State Board of Pharmacy (on behalf of itself, its officers, agents, agencies and departments) agrees to release Cardinal Health 110, Inc., its employees, its current and former parent and affiliated entities from any and all claims and causes of action the Board has asserted, could have asserted, or may have asserted in the future under the statutes for the events and occurrences described in the Recitals section above and/or set forth in the Notice of Opportunity for Hearing dated May 27, 2008, and issued to Cardinal Health 110, Inc. by the Ohio State Board of Pharmacy. In addition, the Board shall release all Cardinal Health entities licensed with the Board as Wholesaler Distributors of Dangerous Drugs and/or Wholesalers of Controlled Substances as defined under Sections 4729.01 and 3719.01 of the Ohio Revised Code from any and all civil administrative actions arising from violations of Rule 4729-9-16(H)(1)(e) of the Ohio Administrative Code and, if proven, constitute violating a rule of the Board within the meaning of Section 4729.56 of the Ohio Revised Code, wherein said violations have occurred or have been alleged to occur before the effective date of this Agreement.

This Settlement Agreement shall be considered a public record, as that term is used in Section 149.43 of the Ohio Revised Code, and shall become effective upon the date of the Board President's signature below.

/s/ Cardinal Health 110 Date Signed: 07/08/08
Respondent

/s/ Robert P. Giacalone, Sr. V.P. and Chief Date Signed: 07/08/08
Regulatory Counsel for Respondent
Attorney for Respondent

/s/ Nathan Lypsyc (sic) 'Lipsyc' Date Signed: 07/08/08
President, Ohio State Board of Pharmacy

/s/ Sally Ann Steuk Date Signed: 07/09/08
Ohio Assistant Attorney General

Attachment 1

Suspicious Order Monitoring System

The Cardinal Health Suspicious Order Monitoring System ("SOM") is designed to meet Cardinal Health's regulatory obligations as established in Rule 4729-9-16(H)(1)(e) of the Ohio Administrative Code and Title 21 CFR §1301.74. Please note that the SOM program described below may be modified in the

future for purposes of enhancing and/or improving the existing system. However, such enhancement(s) shall not adversely affect the identification and reporting capabilities of this SOM program. In addition, SOM program described below outlines the key components of this program and not necessarily all components.

Suspicious Order Monitoring System – Organization

The SOM is organized within the Cardinal Health Compliance Department, headed by the Chief Compliance Officer (“CCO”). Reporting to the CCO is a Senior Vice President, Supply Chain Integrity and Regulatory Operations. Directly responsible for the operation of the SOM is a Vice President of Anti-Diversion and Supply Chain Integrity. The Anti-Diversion SOM Team is further built around two Directors who have significant pharmacy-related experience. The team is then structured around six investigators; four of whom are field based.

In addition to the direct SOM Team, the field Quality and Regulatory Compliance Managers for the pharmaceutical distribution business have been organizationally realigned to report within the Quality and Regulatory Affairs (“QRA”) group that is now a part of the Ethics and Compliance Department. As a result, there is a dedicated field Compliance Manager located in each of the 24 pharmaceutical distribution facilities that distribute controlled substances.

Suspicious Order Monitoring System – Processes

The SOM is functionally organized into key processes:

- Know Your Customer
- Electronic Monitoring
- Account Investigation
- Reporting

The Know Your Customer [KYC] process involves:

- direct communication and/or on-site visits with all new customers and those existing customers where ordering patterns may raise questions are performed on a routine basis by Cardinal Health sales team members and QRA Compliance Managers. The Anti-Diversion SOM Team members also conduct direct communication and on-site visits where warranted.
- the completion of the New Pharmacy Customer Questionnaire. This questionnaire is to elicit information that can be verified with Boards of Pharmacy and Boards of Medicine regarding the principals involved in the pharmacy and those that generate the majority of the prescriptions that are dispensed at the pharmacy.
- an evaluation of historical non-HIPAA¹ dispensing data, if available, or past controlled substances purchasing data for an assessment of the volume of controlled substances that was dispensed or purchased by this potential customer from a prior wholesaler. This provides information as to the seasonality of the purchasing patterns and, if available, assists in the refinement of the thresholds discussed later.

¹ Dispensing data requested from a pharmacy, if available from that pharmacy, will pertain to data that does not contain protected health information (PHI).

- This questionnaire as well as other relevant information forms the basis for the decision whether to conduct additional due diligence and ultimately to engage in a business relationship with a potential customer. Potential customers whose data and information lead to a conclusion that sales of controlled substances constitute an unreasonable risk of diversion are not permitted to purchase controlled substances.

The electronic monitoring process involves:

- the establishment of ordering thresholds. To date, the threshold setting process has involved at least a 3 step process. The first step is to group customers into specific classes of trade (e.g., we have completed this process with retail independent accounts) and then divide them into further subclasses based upon dollar volume. The average for each of these subclasses is calculated and a multiplier is assigned depending upon the schedule and class of the drug. This forms the initial rough approximation of the threshold. The second step is a further refinement to this process for all new customers and for existing customers that trigger and/or may trigger a threshold. This step involves taking the customer's individual purchasing pattern and calculating a monthly average and the standard deviation for the purchasing pattern and adding a multiplier of the standard deviation to the average. The threshold calculated from the first step is compared with the threshold from the second step. The third step is to have a pharmacist analyze the controlled substances thresholds established by each of the methods to see whether there appears to be any anomalies in the data to suggest the potential for drug diversion. If no anomalies are identified, the controlled substances threshold is established. Anomalies identified result in the establishment of a narrow threshold and an on-site investigation by the Anti-Diversion Team.
- the accumulation and blocking of orders. The electronic monitoring system accumulates orders for controlled substances by DEA base code. When the total accumulation of orders exceeds the threshold amount [the identify process], the order and any subsequent order for controlled substances from that family are blocked for the remainder of the month unless the threshold is raised.
- the analysis and reporting of suspicious orders. The first time an order is blocked a Threshold questionnaire is sent to the customer to request an explanation of the threshold order. The information requested is essentially the same information as is requested on the New Customer Questionnaire. The information supplied is then analyzed and verified by the Anti-Diversion Team. If the information provided supports a rational basis for an increase in the threshold, the order is released and the threshold is increased. If the information provided substantiates a one-time need for the controlled substance, the order is released but the threshold is not increased. If the information provided does not substantiate the need for the controlled substance, the order is cancelled, a site visit may be requested and depending upon the analysis by the Anti-Diversion SOM Team of the information obtained, the order may be reported to the DEA and the State Board of Pharmacy as suspicious if it is deemed to be such. Upon further evaluation the customer may be terminated from purchasing any controlled substance where the information provided taken in its totality leads to a conclusion that the continued sales of controlled substances constitutes an unreasonable risk for the diversion of controlled substances from the customer.

- the accumulation of orders for other dangerous drugs subject to abuse as defined by state regulation or Board order undergo a similar analysis and reporting to the Board as described above for controlled substances.

The account investigation process involves:

- the use of field and headquarters staff to visit the customer and seek to discover whether there is evidence of suspicious conduct involving the dispensing of controlled substances;
- the analysis of Internet sites to determine whether there is open and notorious evidence of suspicious conduct on the part of the customer;
- the analysis of the disciplinary history of the pharmacy and principals of the pharmacy including state and federal agencies from resources that are readily available;

The reporting process involves:

- two types of reporting. The first report is a report of orders that meet the plain meaning of the regulation without any inquiry into the order. The regulation requires reports of suspicious orders of:
 - unusual size
 - unusual frequency
 - unusual pattern

The second report is a report of orders where the nature of the order itself or the historical information results in the conclusion that continued shipment of controlled substances to the customer constitutes an unreasonable risk of diversion of controlled substances and that the customer is precluded from the purchase of any controlled substance.
- the report is to be faxed to the field office of the DEA and to the state Board of Pharmacy.

2:10 p.m. Mrs. Gregg moved that the Board receive Per Diem as follows:

<u>PER DIEM</u>	<u>07/07</u>	<u>07/08</u>	<u>Total</u>
Braylock	1	1	2
Casar	1	1	2
Gregg	1	1	2
Kaderly	1	1	2
Kolezynski	1	1	2
Lange	1	1	2
Lipsyc	1	1	2
Pasquale	1	1	2
Wiesenhahn	1	1	2

Mr. Casar seconded the motion and it was approved by the Board: *Aye* – 8.

Mr. Braylock moved that the meeting be adjourned. The motion was seconded by Mr. Kolezynski and approved by the Board: *Aye* – 8.

The Ohio State Board of Pharmacy
approved these Minutes August 5, 2008