

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18

FINAL MINUTES

MEETING OF:

PATIENT SAFETY AUTHORITY

2601 NORTH THIRD STREET
ONE PENN CENTER
HARRISBURG, PENNSYLVANIA

TIME: 9:30 A.M.

FEBRUARY 2, 2004

1

2

Patient Safety Authority

3

February 2, 2004

4 **Board Members:**

5 Robert S. Muscalus, D.O., Chairperson, Physician General
6 The Hon. Mary Ann Dailey
7 Joan M. Garzarelli, MSN
8 Patricia Clancy Kienle, R.Ph.
9 Lorina L. Marshall-Blake (telephone)
10 Danae Powers, M.D.
11 Stanton N. Smullens, M.D.
12 Nathaniel J. Zuckerman, M.D. (telephone)

13

14 **Authority Personnel:**

15 Alan B.K. Rabinowitz, Board Administrator
16 Laurie Baker, Communications Director
17 Sharon Hutton
18 Peter Hoffman, Esquire
19 Joan Plump, Esquire
20 Mike Doering, PA-PSRS Project Manager

21

22 **Also Present:**

23 Jonathan Gaev, PA-PSRS Project Manager, ECRI
24 Roni Solomon, Vice President, ECRI
25 John Clarke, M.D., PA-PSRS Clinical Director, ECRI
26 Badal Sanghvi, PA-PSRS Project Manager, EDS

27

28

1 ***

2 Patient Safety Authority

3 February 2, 2004

4 ***

5 The regularly scheduled meeting of the Patient
6 Safety Authority was held on Monday, February 2, 2004.
7 Robert Muscalus, D.O., Chairman, called the meeting to
8 order at 9:30 a.m.

9 ***

10 Approval of Minutes of the December 8, 2003, meeting

11 DR. SMULLENS:

12 I move to approve the minutes of the
13 December 8, 2003, meeting as submitted.

14 MS. GARZARELLI:

15 Second.

16 DR. MUSCALUS:

17 Any discussion? All in favor of adopting
18 the minutes as submitted indicate by saying
19 aye. Those opposed nay.

20 [The motion carried unanimously.]

21 ***

22 Report of Board Chair

23 [Dr. Muscalus addressed the Board and was pleased to
24 report that, based upon feedback from the 22

1 facilities participating in Phase 1 of the PA-PSRA
2 program, things are "functioning well" and it appears
3 that what the system is designed to do it is
4 performing. Dr. Muscalus concluded his report to note
5 that there is a lot of interest by other states in
6 possibly establishing their own Patient Safety
7 Authority which reemphasizes the fact that
8 Pennsylvania is the first state to establish this type
9 of an entity.]

10 ***

11 Report of Board Administrator

12 [Alan B.K. Rabinowitz addressed the Board to provide
13 the following update concerning Phase 1 which
14 commenced November 17, 2003, and will run through
15 March 12, 2004: As of November 17, 2003, through
16 January 28, 2004, 1,822 reports of both serious events
17 and incidents have been submitted to the Authority
18 from the 22 participating facilities, with 96%
19 comprising incidents and 4% comprising serious events.
20 He noted that, since the 22 facilities participating
21 in Phase 1 are doing so voluntarily, these statistics
22 are probably incomplete and should not be cited as
23 accurately reflecting actual events. He also noted

1 that, based on feedback and a user survey, the
2 facilities seemed pleased with the reporting system.
3 Because of recent news articles highlighting the
4 problem of hospital-acquired infections, Mr.
5 Rabinowitz noted that the Authority is receiving
6 reports of nosocomial (hospital-based) infections as
7 part of Phase 1. Dr. Muscalus provided clarification
8 that PA-PSRS does allow a facility to report a
9 nosocomial infection when it meets Act 13's definition
10 of a serious event or incident and also that the
11 system is able to identify that specific category of
12 hospital-acquired infections as a separate entity
13 within the reporting system.

14 Mr. Rabinowitz provided the Board with the timeline
15 for Phase 2 that will commence March 15, 2004, and the
16 statewide rollout of PA-PSRS as follows: All 400
17 facilities will be broken down into three regional
18 groups (eastern, central and western), training will
19 begin on 4/26/04 for the first group with the idea
20 that about a month after a facility has been trained
21 they will be required to begin providing mandatory
22 reports, and it is anticipated that all 400 facilities
23 will be providing mandatory reports online no later

1 than June 28, 2004. Dr. Muscalus reiterated the fact
2 that there will be ample number of training sessions
3 and plenty of opportunity for the facilities' staff to
4 be trained in order to meet the legal requirement to
5 begin reporting. Mr. Rabinowitz further noted the
6 following: The 22 facilities are being called in for a
7 training session on March 11, 2004, with respect to
8 Phase 2; Phase 2 will now provide facilities access to
9 all the analytical capacity that the system has; the
10 Department of Health is working with EDS and ECRI to
11 finalize the infrastructure failure report submission
12 form. Dr. Muscalus pointed out that some facilities
13 have internal reporting systems in place and that the
14 Authority will in time be interested in learning more
15 about these systems, how many of them there are and
16 what opportunities exist for some type of integration
17 of their system into PSRS. Mr. Rabinowitz also
18 reported that the Department of Health will begin
19 receiving "live data" beginning March 15, 2004,
20 and that the Department of Health will be modifying
21 its current electronic reporting system to receive the
22 Authority's data and reconfigure the data so that they
23 can use it for their own purposes and their own

1 system.

2 Mr. Rabinowitz concluded by noting the following

3 modifications that have been made to the reporting

4 questionnaire: Removal of the phrase "In your own

5 words" in connection with narrative texts, the

6 addition of a subset for "failure of omission," the

7 inclusion of checkoffs for staff proficiency/staff

8 impairment, modification of the anonymous report form,

9 inclusion of a date that confirms the serious event or

10 infrastructure failure, and retaining the word "error"

11 on the questionnaire, along with a dozen or so changes

12 that clarify language or eliminate abbreviations. Dr.

13 Muscalus pointed out that the PSRS program staff

14 looked very closely at use of the word "error" but was

15 unable to identifyf a concise alternative phrase.

16 Also, none of the 22 facilities have voiced no concern

17 over use of the term, so it was determined to stay

18 with "error," at least for now. Dr. Smullens noted

19 that he is still interested in and will investigate

20 whether the word "error" could be replaced with

21 another word or phrase. Dr. Muscalus advised the

22 Board that the most significant change that will be

23 made to the report form is that there will be no

1 optional questions for the reporting of serious events
2 and infrastructure failure per the Department of
3 Health, which is requiring that all questions be
4 required. He noted, however, that due to the fact
5 that facilities may not always know the answers to
6 some of the questions pertaining to serious events and
7 infrastructure failures within the timeframe they have
8 to submit the report, additional options of "To be
9 determined" or "Not applicable" are being included in
10 the questions. Ms. Garzarelli expressed concern over
11 the fact that, if all information is mandatory,
12 facilities will no longer feel compelled to conduct a
13 credible, thorough, root cause analysis or that they
14 will be reluctant to provide the "good information"
15 unless there's some "forcing function in the system."
16 Dr. Smullens expressed his concern over the optional
17 questions now being mandatory and suggested that the
18 Department of Health "rethink this approach." There
19 was continued discussion among numerous Board members
20 on this issue. Representative Dailey asked that the
21 minutes "reflect" the Board's concerns. Dr. Muscalus
22 suggested that the Authority "use those minutes to
23 communicate [the Board's concerns] to the Department

1 of Health."]

2

3 [Dr. John Combes, who identified himself as Senior
4 Medical Advisor to the Hospital and Healthsystem
5 Association of Pennsylvania, expressed his concern
6 over the optional questions now being mandatory by
7 pointing out that this may carryover to
8 facilities refraining from including details on the
9 incident reports which may therefore limit the
10 usefulness of these "valuable learning tools" in terms
11 of making necessary improvements.]

12

13 [Discussion was held concerning whether there could be
14 two types of reports of serious events with different
15 levels of detail, one to the Department of Health and
16 one to the Patient Safety Authority. Ms. Plump
17 advised the Board that the statute does not allow for
18 two versions of serious events. There was also
19 discussion of "accountability systems" versus
20 "learning systems." Dr. Don Harrup, who identified
21 himself as representing the Pennsylvania Medical
22 Society, briefly commented on the importance of a
23 learning system to maintain the Authority's

1 credibility.]

2 ***

3 Report of the Communications Director

4 [Laurie Baker addressed the Board at 11:35 a.m. to
5 note that her overall message is moving from the
6 culture of blame to one of learning. She noted the
7 following with regard to her communications plan,
8 which she noted is a work in progress: She will be
9 corresponding with the participating 22 facilities in
10 the very near future concerning the March 11, 2004,
11 Phase 2 training session and the remainder of
12 facilities will also be notified concerning their
13 participation in training sessions; she plans to do
14 press conferences and news releases; the annual report
15 is due to the General Assembly on May 1, 2004. She
16 also noted that her plans for June through December
17 include compiling and sending a PSA message editorial
18 from Dr. Muscalus, continued speaking engagements by
19 Dr. Muscalus and PSA newsletter/brochure updates.]

20 ***

21 Old Business - No Report

22 ***

23 Other New Business - No Report

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

Adjournment

MS. KIENLE:

I move to adjourn.

MS. MARSHALL-BLAKE:

Second.

DR. MUSCALUS:

Discussion? All those in favor indicate by
saying aye. Those opposed nay.

[The motion carried unanimously.]

[The meeting was adjourned at 11:43 a.m.]

Brad Weirich,
Minute Clerk,
York Stenographic Services

York Stenographic Services, Inc.
34 North George St., York, PA 17401 - (717) 854-0077

1 adm

| 5 | TIME | COUNTER | AGENDA |
|----|-------|---------|---|
| 6 | | NUMBER | |
| 1 | | | PATIENT SAFETY AUTHORITY |
| 2 | | | REFERENCE INDEX |
| 3 | | | FEBRUARY 2, 2004 |
| 4 | | | |
| 8 | 9:30 | 0038 | Call to Order, Robert Muscalus, D.O., Chairman |
| 9 | | | |
| 10 | | | |
| 11 | 9:31 | 0045 | Approval of Minutes of the December 8, 2003, meeting |
| 12 | | | |
| 13 | | | |
| 14 | 9:32 | 0088 | Report of Board Chairman, Robert Muscalus, D.O. |
| 15 | | | |
| 16 | | | |
| 17 | 9:34 | 0177 | Report of Board Administrator, Alan B.K. Rabinowitz |
| 18 | | | |
| 19 | | | |
| 20 | 11:35 | 5970 | Report of the Communications Director, Laurie Baker |
| 21 | | | |
| 22 | | | |
| 23 | 11:43 | | Adjournment |